RHYTHMIC AUDITORY STIMULATION FOR GAIT TRAINING IN PERSONS WITH UNILATERAL TRANSTIBIAL AMPUTATION: A RANDOMIZED CONTROLLED TRIAL

Dissertation submitted to the Tamil Nadu Dr. MGR Medical University,

Chennai, in partial fulfilment of requirements for the MD Branch XIX

(Physical Medicine and Rehabilitation) examination in March 2015

DECLARATION

I hereby declare that "Rhythmic auditory stimulation for gait training in persons with unilateral transtibial amputation: A Randomized Controlled Trial" is my bona fide work in partial fulfilment of the requirement of the Tamil Nadu Dr MGR Medical University, Chennai, for the MD Branch XIX (Physical Medicine and Rehabilitation) examination in March 2015.

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CERTIFICATE

This is to certify that “Rhythmic auditory stimulation for gait training in persons with unilateral transtibial amputation: A Randomized Controlled Trial” is the bona fide work of Dr. Lahunlang Millian Sohliya, Candidate Number 201229054, in partial fulfilment of the requirement of the Tamil Nadu Dr MGR Medical University, Chennai, for the MD Branch XIX (Physical Medicine and Rehabilitation) examination in March 2015, done under my supervision and guidance.

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Dr. Alfred Job Daniel

Principal

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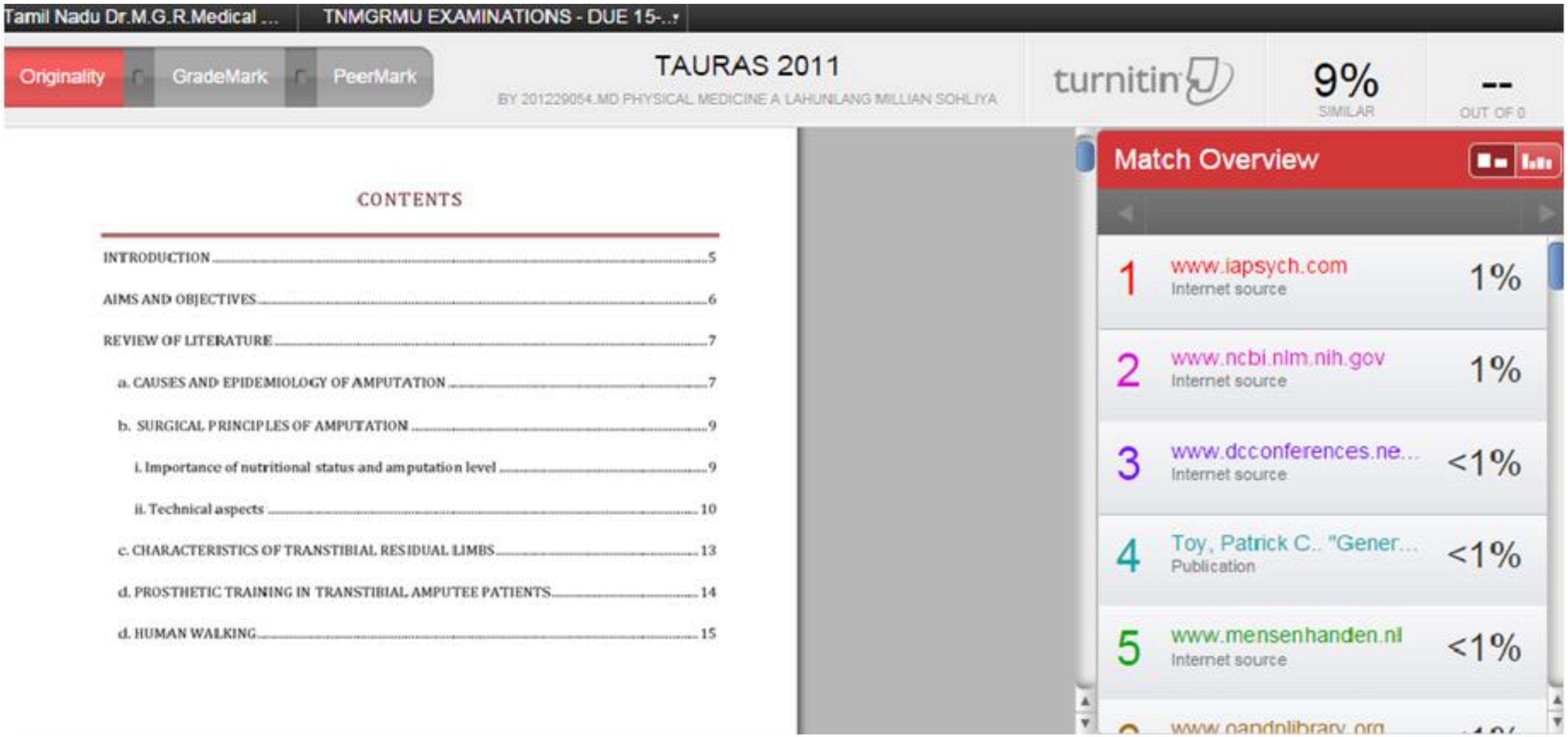
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TITLE OF THE STUDY

Rhythmic auditory stimulation for gait training in persons with unilateral transtibial amputation: A Randomized Controlled Trial

Place of study

Department of Physical Medicine and Rehabilitation

Christian Medical College, Vellore

ABSTRACT

Rhythmic auditory stimulation for gait training in persons with unilateral transtibial amputation: A Randomized Controlled Trial

Department of Physical Medicine and Rehabilitation

Lahunlang Millian Sohliya

MD Physical Medicine and Rehabilitation

Dr. Raji Thomas (guide)

OBJECTIVES

To compare the time taken for prosthetic training using Rhythmic Auditory Stimulation with that of conventional therapy, for unilateral transtibial amputee patients

To compare the gait parameters in unilateral transtibial amputee patients trained with and without Rhythmic Auditory Stimulation

METHOD OF THE STUDY

44 patients were enrolled in the study out of which 15 patients dropped out, the most common reason being due to ulcers present in the residual limb. A total of 29 patients continued on with prosthetic training of which 13 were in the RAS group and 16 in the control group. Those in the RAS group received rhythmic beats introduced through MP3

players and earphones during prosthetic training for one hour daily. Conventional prosthetic training was carried out for those in the control group for the same duration every day. On completion of training as per defined criteria, the outcome measures were analysed by a blinded assessor. Primary outcome measures included time to complete training, timed up and go (TUG) test and 6MWT while secondary outcome measures included gait velocity, gait cadence, step length, stride length, symmetry, stance swing ratio, single limb support and physiological cost index (PCI). Kinetic analysis was done in 9 patients. The outcome measures were statistically analysed by the Independent sample T test.

RESULTS

1. RAS enhanced prosthetic training decreased time required to complete training (6.08 hours) in transtibial amputee patients compared to conventional therapy (7.44 hours) though the result was not statistically significant.

2. In the TUG test and 6MWT, patients in the RAS group did better (TUG 11.09 s, 6MWT 323.37 m) than those in the control group(TUG 13.43, 6MWT 288.96 m). Though no statistical significance could be derived, the potential of RAS to improve walking endurance was noticed.

3. Because of external cueing possibly leading to “forced gait”, step length was found to be significantly better for those in the control group (p value 0.016 in the amputated limb, 0.019 in the normal limb). RAS may not be effective in improving step length in transtibial amputee patients.

4. On doing a sub-analysis excluding two patients whose results skewed the data, statistical significance was found for the TUG test (p value 0.020) and percentage decrease from

regression to 6 minute walk(p value 0.038) for patients in the RAS group as compared to the control group. Most parameters were found to be better in the RAS group.

5. Patients in the RAS group finished training in a significantly shorter time when they used slower frequency beats (p value 0.03). 6MWT of statistical significance (p value 0.01) was seen with the use of higher frequency beats.

1 INTRODUCTION

The physical loss of a body part can result in significant changes in body structure and function, cause loss of self-confidence and hinder social and daily activities. One of the major needs of a person who has undergone an amputation is to regain the ability to walk again, independently. To achieve this, the individual is given a prosthesis which is by definition an artificial substitute for a missing body part. It compensates for the loss of body structure and function.

Training a patient to walk again can be a challenge. An amputee gait differs from a normal gait in having less velocity, cadence, stride and step length with associated discrepancy between prosthetic and sound leg.(1)Addressing the problem and making a person mobile again can bring a dramatic change in the Quality of Life (QoL) of the individual as well as of the family members.

The aesthetic and spiritual qualities of music have always been the base of using music in the medical field. It was not until the recent years that the neurophysiology and circuitry of pathways leading to the actual effect of music on the human brain and body were studied. The knowledge accumulated in the past two decades suggest that music can stimulate complex cognitive, affective, and sensorimotor processes in the brain that can be generalized and transferred to non-musical therapeutic applications.(2) Studies in this field are still a matter of ongoing research.

The study of rhythm which is one of the most important elements of music has produced insights into musical time processing and temporal information processing in the human brain. Rhythmic auditory stimulation (RAS) is believed to be based on the mechanism of rhythmic entrainment and priming of auditory pathway. The physiological basis is detection of periodicity patterns in amplitude modulation of sound. Enhancement of gait is mediated by an entrainment effect where movement frequency and motor programming entrain to rhythm in anticipatory cueing of final movement patterns.

For metronomes, immediate carry over effects from walking with to walking without cues have been reported for walking speed, cadence, stride length and symmetry of gait in patients with Cerebrovascular accidents, Parkinson's disease and traumatic brain injury. This has been extrapolated from the idea that RAS influences the brains' oscillator and time keeper functions that regulate gait. Patients achieve a final gait pattern which then transfers to walking without external cueing.

Based on this concept, we introduce the possibility of using rhythmic auditory stimulation for prosthetic gait training of amputee patients. Two groups of patients will be studied. Both groups will comprise of patients with unilateral transtibial amputation who fall within the inclusion criteria. The study group will receive rhythmic beats through external earphones for every session of prosthetic training. The control group will undergoprosthetic training as is currently being practised, without the use of rhythmic beats. The primary outcome measure will be time taken to complete training (measured in hours), time to complete the Timed Up and Go (TUG) test and 6 minute Walk test (6MWT). Secondary outcome measures will be temporal gait parameters and energy efficiency which will be assessed at a Human motion analysis lab. These outcome measures will help define any statistically significant difference between the two groups. If found to be significant, this method of training can be introduced into future prosthetic training programmes for amputee patients.

2 AIMS AND OBJECTIVES

AIM:

To evaluate the usefulness of Rhythmic Auditory Stimulation (RAS) for prosthetic training in patients with unilateral transtibial amputation

OBJECTIVES:

- To compare the time taken for prosthetic training using Rhythmic Auditory Stimulation with that for conventional therapy for unilateral transtibial amputee patients.
- To compare the gait parameters in unilateral transtibial amputee patients trained with and without Rhythmic Auditory Stimulation

3 REVIEW OF LITERATURE

3.1 CAUSES AND EPIDEMIOLOGY OF AMPUTATION

Amputation can be the outcome of unforeseen disasters like trauma and road traffic accidents, chronic or acute medical illnesses where the limb cannot be salvaged, natural calamities, accidents at the workplace, sports injuries, congenital deficiencies, terrorism and war. Incidence varies from country to country. The leading causes of amputation in developed countries are artero-occlusive vascular diseases, diabetes and tumours accounting for 68% of amputations annually. In developing countries, trauma related accidents including motor vehicle, industrial or farming accidents are the leading causes of amputations accounting for 30% of new limb amputations.(3)

Incidence and Prevalence: The worldwide prevalence of amputation rates is difficult to ascertain as many countries do not keep tabulated records of amputation cases. The incidence of amputation increases steeply with ages above 60, the major causes being trauma and cancer (4)and is higher in men than in women.(5)

- **Road traffic accidents**: The GlobalStatus Report on Road Safety 2013 presents information from 182 countries. It indicates that worldwide the total number of road accidents leading to death is still at a high of 1.24million per year. In India, the incidence of deaths due to road accidents is 16.8 per 100,000 population(4) and 13.8 non-fatal accidents per 100,000. From these figures, it is postulated that road traffic accidents leading to traumatic amputations holds a significant percentage. Apart from road accidents, train accidents due to overcrowding also hold a percentage of amputation causes.

- **Diabetes Mellitus**: Currently, 135 million people around the world have diabetes and more than 62million (more than 7.1% of the adult population) Indians are affected by it.(6) By the year 2030AD, India (the current diabetic capital of the world) is expected to have the largest number of diabetic patients surpassing the 92million of China. Diabetes related lower extremity amputation rates have been found to be 12.5 to 31.6 times that of persons without diabetes.(7)Diabetic foot is one of the common diabetic complications found in India.(8) Each year, 40,000 individuals undergo lower limb amputations due to diabetic complications.(4)However, it is only second to traumatic accidents as the major cause of lower limb amputations in India. In a multi-centric study done in India, the leading cause of amputation among diabetic patients was found to be infection. Among those who underwent major amputations, more than 50% were below knee amputations and 11.9% above knee amputations. Of the total number of amputations, over half of them were of toes and rays.(9)

- In the Western world, peripheral vascular diseases(PVD) with or without diabetes account for 80-90% of amputations.(4) In a study done in the Indian population(10) the overall prevalence of PVD was found to be considerably lower compared to the western population.

3.2 SURGICAL PRINCIPLES OF AMPUTATION

3.2.1 IMPORTANCE OF NUTRITIONAL STATUS AND AMPUTATION LEVEL

Studies done by Dickhautet.al and Kay et al. reported uneventful healing of amputations in 15 of 16 patients with normal nutritional parameters whereas 11 of 25 malnourished patients had postoperative complications including ulcers. It was concluded that lower healing rates and higher postoperative complications will be seen in patients with serum albumin levels less than 3.5g/dL and total lymphocyte count of at least 1500 cells/ml.(11)

Waters et al. studied the energy cost of walking for patients with amputations at different levels. On comparing with controls without amputations, they confirmed that the lower the level of amputation, the better the performance. It is understood that amputation should be performed at the lowest level possible if preservation of function is the chief concern.(12)

3.2.2 TECHNICAL ASPECTS

The ideal stump length is between 12.5cm to 17.5cm. As it may vary according to height, allowing 2.5cm bone length for every 30cm of height gives a satisfactory measurement. The most acceptable length is 15cm distal to the medial tibial articular surface.(13)

With the modern total contact prosthetic sockets which are being used now, the location of the scar is not of major importance as long as the scar does not adhere to the underlying bone. This is because an adherent scar causes difficulty in fitting the prosthesis and often breaks down after prolonged prosthesis use. Redundant soft tissues or “dog ears” also create problems in prosthetic fitting.

Muscles after resection from their origin are usually stabilized by Myodesis (suturing muscle or tendon to bone) or Myoplasty (suturing muscle to periosteum or to fascia of opposing musculature). The preferred method if possible is Myodesis as it provides a stronger insertion which in turn maximizes strength and minimizes muscle atrophy, maximizes residual limb function and is more effective for preventing contractures. Its use in limb ischemia is however contraindicated because of increased risk of wound breakdown.(13)

3.2.3 STAGED AMPUTATIONS

Staged (two-staged) amputations are done in cases of infection and severe trauma. In such cases, debridement or stump preparation in the form of an open “guillotine” amputation is the first of at least two operations. This is always followed by secondary closure, re-amputation, revision or plastic repair.(14,15)

3.2.4 TECHNIQUES SPECIFIC TO BELOW KNEE AMPUTATIONS

1. Posterior flap technique - This is the most common technique preferred for transtibial amputation. The advantage of this flap is placement of the scar in a non-weight bearing surface.(16) A study done in 1976 by Mooney V et al. also confirmed that this technique offered a significant advantage in healing rate.(17)The disadvantage however is the potential for ischemia in the flap area.
2. Skew technique – This is based on equal anteromedial and posterolateral fasciocutaneous flaps. Useful if there is inadequate skin to create a posterior flap.(18)
3. Saggital – In this technique, equal medial and lateral myocutaneous flaps are created.(19)
4. Medial - This technique constructs a long medial and a short lateral flap.(20)
5. Medial –Fish mouth – This method is based on equal anterior and posterior flaps.

3.2.5 COMPLICATIONS

Complications following amputation include medical complications like cardiac and pulmonary conditions and can also be local complications related to the residual limb including infection, incessant pain, post-operative pain and others which may need re-exploration. Some of the most common complications we see according to their frequency are stated below:

- Ulcers – Bony edges which are not rasped or smoothened out can be one of the major causes of ulcer complications especially in bony prominences such as anterior aspect of tibia for transtibial amputations and lateral aspect of femur for transfemoral amputations.(13) Residual limb skin conditions are also another major aspect determining the development of ulcers. Levy in 1956 was one of the earliest researchers in this field where he emphasized that skin problems (folliculitis, contact dermatitis, stump edema syndrome, epidermoid cysts) and stump hygiene should not be overlooked in an amputee patient. During weight bearing, the skin is exposed to shear forces which cause repeated ulcerations at the stump prosthesis interface. This can be exaggerated with poor nutritional status, vascular insufficiency, poor stump hygiene and inadequate pressure relieving points on an ill-fitting prosthesis.(21)

- A study done by Berridge DC etal. on a hundred amputees with ischemia reported that 13 – 40% patients with pre-operative infections, low nutritional status, advanced age and wound hematomas developed infections. There was no significant difference in wound sepsis rates of diabetic patients.(22)

- Phantom limb pain – It is defined as a burning, aching, electric-type pain on the amputated limb. In a questionnaire for 5000 American veterans done in 2005, 78% reported phantom pain. Of those receiving treatment only 1% reported any long last benefit.(23)

- It was reported that 10-20% of patients who had undergone below knee amputation needed re-amputation at the femoral level. Diabetic patients were more prone to higher level re-amputations than on diabetic patients.(24)

- Neuroma- A neuroma is formed when a nerve has been divided. It becomes painful when it is located in an area which exposes it to repeated pressure and trauma. Different methods of isolating and burying the nerve are being practiced. Strong tension and crushing should be avoided.(13)

3.3 CHARACTERISTICS OF TRANSTIBIAL RESIDUAL LIMBS

It is imperative that residual limbs have certain characteristics which make them adaptable to transtibial prostheses. The residual limb characteristics, length of residual limb, range of motion at the adjacent joint/presence of any contractures or deformities, individuals' goals and activities, individuals' geographic location are some of the important factors needed for determining the prosthetic socket fitting and suspension methods.(25)

Characteristics of the residual limbs include skin condition, volume (edematous changes), location and condition of surgical scar. Residual limb length may vary between long (more than 80% of the normal limb), medium (50% of the normal limb) or short (less than 30% of the normal limb).

An ideal stump should have the following characteristics:

- An ideal length and shape

- A non-adherent incision scar
- All bony end margins should be well covered by muscle and skin
- It should be free from any open wound or infection
- Neuromas should be absent
- There should not be any joint contracture or deformity
- There should be full range of motion at the joint above it

3.4 TRANSTIBIAL PROSTHESIS

When lower limb prostheses are prescribed, the following principles should be remembered:

- The mobility needs of the particular patient are met
- Maximal comfort with no pain caused by the socket on the residual limb. A poorly fitting prosthesis with an uncomfortable socket will lead to limited mobility and higher chances of rejection of the prosthesis
- Correct choice of components for achieving maximal independence and functional mobility
- Acceptable cosmetic appearance

Transtibial prostheses are comprised of the following components:

- A socket with silicone liner system which maximizes the comfort and minimizes chances of ulceration at the area of the residual limb which comes in direct contact with it. The patellar tendon bearing (PTB) socket is the most commonly used socket design. Variations of it are the PTB-SC (Supracondylar) and PTB-SCSP (Supracondylar Suprapatellar) sockets. They are most useful for patients with short residual limbs. Other alternative sockets such as the total surface bearing (TSB) and hydrostatic sockets are being increasingly accepted.(26)

- The suspension system includes straps (most commonly Supracondylar cuff strap), prosthetic sleeves, suction and gel liners with locking mechanisms.(27) Sleeve suspension consists of elastic sleeves, rubber or neoprene which are pulled up over the thigh after donning the prosthesis.(28) Gel liners reduce shear which make them the option of choice in residual limbs with compromised skin integrity or those with skin grafts. The suction suspension system works through a partial vacuum which is created by an air valve present at the bottom of the prosthesis with an air tight sleeve.(29)

- An endoskeletal pylon is most commonly used. It allows further alteration if needed after fabrication of the prosthesis. It absorbs shock on impact and helps reduce energy expenditure.

- A suitable prosthetic foot completes the transtibial prosthesis. It can be basic, articulated or dynamic response. Solid Ankle Cushion Heel (SACH) foot is the most commonly and widely accepted basic prosthetic foot. Articulated prosthetic feet come as single axial or multi-axial joints. Dynamic response feet help in push off and decrease force of impact of the other foot with the ground.(27)

3.5 PROSTHETIC TRAINING IN TRANSTIBIAL AMPUTEE PATIENTS

"If we all did things we are capable of doing, we would literally astound ourselves."

Thomas Alva Edison

Persons with amputated lower limbs and new prostheses many a time believe that they are individually capable of walking without the need of gait training. Though positive attitude goes a long way in helping them ambulate, gait training is also necessary to achieve a smooth and more importantly safe gait. To achieve this, the steps to be followed are broadly divided into: (30)

1. Weight bearing and balance training – Partial weight bearing progressing to full weight bearing, side walking within parallel bars with or without support, balance board, obstacle stepping
2. Specific gait training- Alternate step forward of sound leg and prosthetic leg progressing to walking within parallel bars with or without support
3. Advanced exercises – Walking on an uneven surface, negotiating ramps and slopes, running
4. Functional exercises – Negotiating stairs, independent transfers from bed, chair and floor

Certain factors contribute to the success of prosthetic mobility training. Davies and Datta in their study "Mobility outcome following lower limb amputation" stated that chances of prosthetic mobility decreased with increasing age.(31) They also stated that almost all unilateral transtibial amputees less than 50 years of age attained community mobility whereas only 50% of those more than 50 years of age attained community mobility.

Another study done on 46 patients with below knee amputations stated that the rate of progression with temporary prosthesis was correlated with age and rate of healing.(32)

3.6 HUMAN WALKING

Walking is a method of bipedal locomotion involving the use of two legs alternately to provide both support and propulsion with at least one foot in contact with the ground at all times. Each individual can be distinguished by their gait as it is unique to every person. When a problem arises within the body, such as in amputation of a limb, repetition of the gait cycle is disturbed. To overcome this, certain techniques are adopted to carry oneself during walking.

Gait cycle and a repetition of gait cycles compose smooth human walking. To better understand this, we will look at gait in different sections.

Phases of gait

One gait cycle is defined as the initial contact of the foot to successive ipsilateral initial contact. Gait cycle is divided into two phases: the stance phase (60%) and swing phase (40%). The subdivision in each phase is elaborated in Figure3.1 and Table 3.1

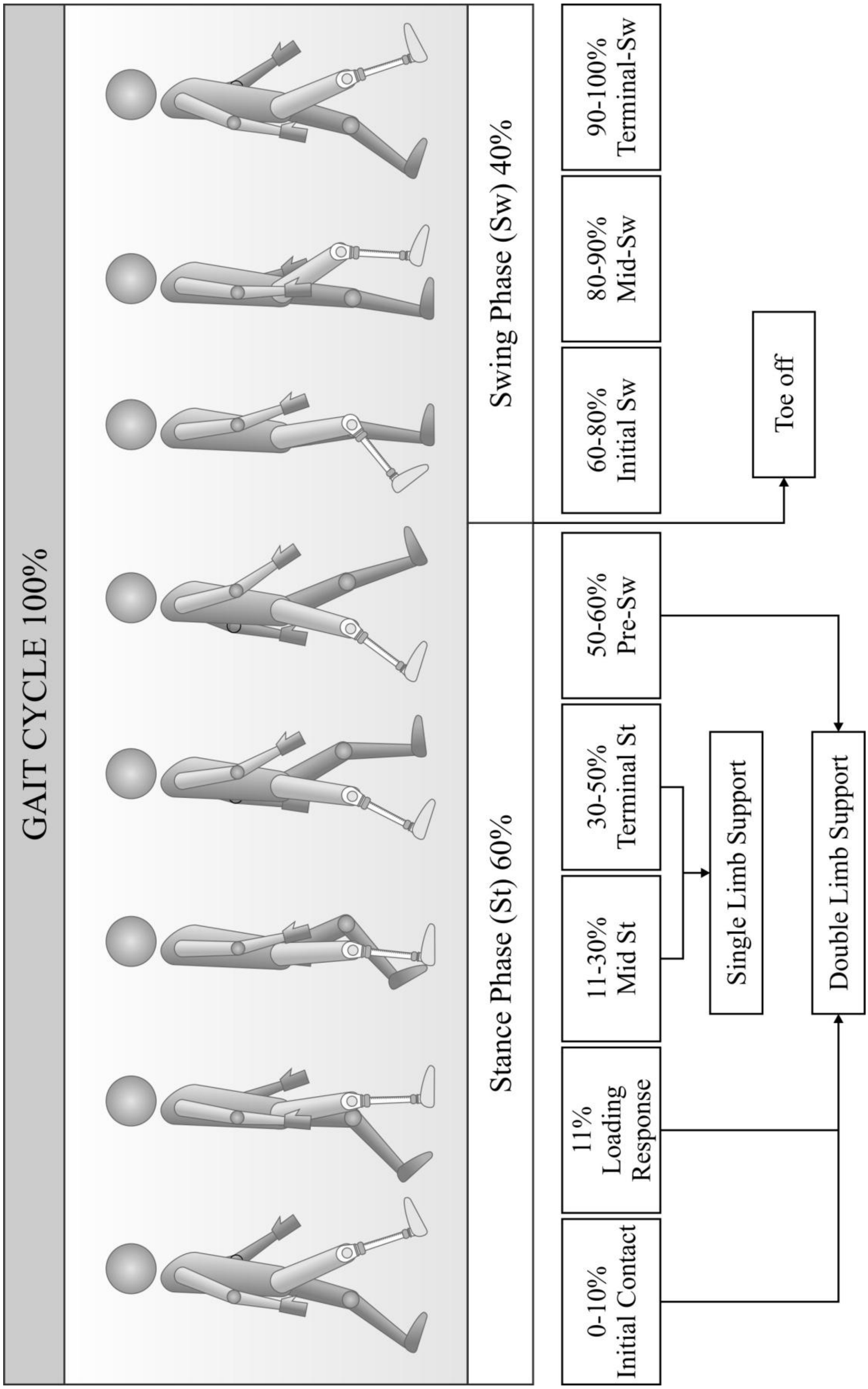


FIGURE 3.1 - GAIT CYCLE IN A RIGHT UNILATERAL TRANSTIBIAL AMPUTEE

TABLE 3.1 - ACTION OF THE ANKLE, KNEE AND HIP IN DIFFERENT PHASES OF GAIT

STANCE PHASE(60%)		**SWING PHASE (40%)**	
Initial contact (IC) (0-10%)	A: Foot strikes ground. Ankle in DF K: In extension H: 40 ° flexed	Initial swing (ISw) (60-80%)	A: DF K: Rapid flexion H: Neutral to flexion
Loading response (LR) (11%)	A: Heel rocker K: Start flexing H: Begins extending		
Mid stance (MSt) (11-30%)	A: Ankle rocker K: Coming to neutral H: Controlled extension	Mid swing (MSw) (80-90%)	A: DF K: Extension H: Flexion
Terminal Stance (TSt) (30-50%)	A: Forefoot rocker K: Full extension H: Hyperextension		
Pre swing (PSw) (50-60%)	A:PF K: Starts flexing H: Starts flexing	Terminal swing (TSw) (90-100%)	A:DF to neutral K: Extension H: Flexion

A-Ankle; K- Knee; H-Hip; DF- Dorsi flexion; TA- Tibialis Anterior; PF- Plantar flexion

Gait stability in stance

Based on contact of foot with the floor, the gait cycle can also be divided into ***single limb support*** and ***double limb support***.

TABLE 3.2 - DESCRIBING SINGLE LIMB SUPPORT AND DOUBLE LIMB SUPPORT

Single limb support(SLS)	**Double limb support (DLS)**
The period in which one limb is in contact with the floor	The period in which both feet are in contact with the floor
Occurs ***once*** during each cycle	Occurs ***twice*** during each cycle
Accounts for 80% of the gait cycle	Each DLS accounts for 11% of gait cycle Total DLS 20-22% during each cycle

Different parameters of gait

1. Gait velocity (47 ± 15m/min*)- A measure of ambulation speed calculated as the distance walked in a minute
2. Gait cadence – Number of steps in a period of time, commonly expressed as steps per minute
3. Step length – Distance between the feet in the direction of progression covered during one step
4. Stride length(84 ± 18cm*)–The distance between the same foot in the direction of progression during one stride
5. Stance swing ratio (60:40) – The ratio of 60% stance to 40% swing where the stance foot side is in direct contact with the ground and the swing foot side swings

through to take the next step. It is affected in gait deviations causing increased instability and decreased velocity.

6. Single limb support (40 ± 5%*)– Measured as the percentage of weight bearing on a single lower limb
7. Symmetry - A measure of step lengths comparing the normal and the unaffected sides calculated by the formula:

$$\frac{\boldsymbol{Step\ length\ (unaffected\ limb) - Step\ length\ (affected\ limb)}}{\boldsymbol{Step\ length\ (unaffected\ limb)}}$$

EQUATION 3.1 - SYMMETRY

*Normal values extrapolated from the data of ten 5-15 year olds in a study done in the movement analysis laboratory, Rehabilitation Institute, CMC Vellore, 1998.

Determinants of gait(Saunders 1953)

They produce forward progression with the least energy expenditure

TABLE 3.3 - DESCRIBING THE SIX DETERMINANTS OF GAIT (27)

1.PELVIC ROTATION	Pelvis rotates medially to the swinging leg side, lengthening the leg on that side and preventing sudden drop in CoG by a 4° pelvic rotation during DLS.
2.PELVIC TILT	Pelvis on the swinging side lowers by 4-5° which lowers the CoG at midstance
3.KNEE FLEXION IN STANCE	Knee flexes 15° at heel strike(IC). Reduces the vertical elevation of the body at MSt. This lowers the CoG minimizing energy expenditure. Also acts as shock absorption at the time of IC
4.ANKLE MECHANISMS	Weight transfer from heel to flat foot associated with controlled PF of the foot during first part of stance
5.KNEE MECHANISMS	Knee flexes 30-40° during last part of stance before going into extension as ankle goes into PF
6.LATERAL DISPLACEMENT OF PELVIS	Displacement towards stance limb. Reduces the horizontal displacement of the CoG

CoG- Centre of Gravity; DLS- Double limb support; IC-Initial contact; MSt-Midstance; DF- Dorsiflexion; PF- Plantarflexion

Energy efficiency

Energy efficiency is measured by the Physiological Cost Index (PCI). In 1979, MacGregor suggested a simple, non-invasive way of measuring physiological cost of walking. It is based on the linear relation between heart rate and walking speed to Oxygen consumption. It is calculated by the formula:

$$\boldsymbol{PCI\ (beats/m)} = \frac{\boldsymbol{Walking\ heart\ rate - Resting\ heart\ rate\ (beats/min)}}{\boldsymbol{Average\ walking\ speed\ (m/min)}}$$

EQUATION 3.2 - PHYSIOLOGICAL COST INDEX

3.7 GAIT ANALYSIS

The concept of depicting human motion was introduced during the Renaissance period. Giovanni Alfonso Borelli a student of Galileo was one of the pioneers in analyzing motion while developing his theory of muscle action based on mechanical principles. In 1872, Eadweard Muybridge attempted taking a still photograph of a running horse with all four feet off the ground. Years later, a sequence of still photographs could be produced. This was the beginning of gait analysis.(33)

The following are the components of gait analysis:(34)

1. **Video gait analysis**–Visual analysis is a qualitative study performed to develop the initial examination of a patient. In slow motion analysis and frame to frame analysis, various measurements can be made. This can yield good descriptive information. The limitations are the possibility of human error.
2. **Kinematics**–It describes the spatial movement of the body. Data is collected from infrared LEDs which are placed over the joints of a patients' body.

3. **Kinetics**–It deals with forces which are produced during walking. It follows Newton's third law where *"every reaction has an equal and opposite reaction"*. This means that the ground reaction force (GRF) is a reaction of the body weight and acceleration. The data is collected when the patient steps on a force plate which measures the force of the foot exerted on it.
4. **Dynamic electromyography** - It is a more discriminating technique which helps to define which muscle is in action for a certain movement of the joint. It is measured through surface EMGs which are attached superficially over the skin. They detect the electrical signals that activate muscle fibers.
5. **Energy consumption** - Energy is consumed during walking and is conserved by activating only the muscles which are needed for a certain movement. It is a measure of how much energy is spent on a certain activity. It is increased in case of abnormalities of gait because of a disturbance in the determinants of gait responsible for energy conservation.

3.8 STUDIES OF GAIT IN TRANSTIBIAL AMPUTEE PATIENTS

The different parameters of gait in an individual with a lower limb amputation differs from that of an able bodied person.(35) International studies comparing the gait of individuals with transtibial amputations, have reported decreased cadence, shorter stride and step length, wider step width, slower walking speed and longer time to initiate gait.(1) There is also asymmetry between the prosthetic limb and sound limb. Step time, step length and swing time were longer whereas stride length and stance time were shorter on the prosthetic limb compared to the intact limb.(36)

Variations in gait according to cause of amputation have also been studied. Gait performance of vascular amputees were found to differ from that of traumatic amputees, a difference that was not caused by reduced walking speed.(37) The disparity was in the difference in push off, where those with vascular causes lacked active forces which were present in healthy and traumatic gait. This could be attributed to the effect of the systemic disease.

Studies measuring gait parameters in the Indian population are few. One such study done to quantify the differences between transtibial amputee gait and able bodied gait at different walking speeds showed significant reduction ($p<0.5$) in speed, cadence and parameters including single limb support on prosthetic limb and step length. Time during double limb support and single limb support on sound limb were augmented ($p<0.5$). However, there did not seem to be any significant effect ($p<0.88$) on the gait efficiency, though a gradual drop of PCI with speed increment was seen, indicating better efficiency at higher walking speeds.(38)

Another Indian based study looked into the effect of residual limb length on gait parameters. It was found that amputee patients with longer stump length (54.2%-64.6% of the sound limb length) had more efficient gait in terms of less energy consumption, more velocity and more cadence in comparison to those with shorter stump lengths. Gait and prosthesis efficiency were also evidently more as there was better skin protection and longer lever arm for prosthesis fitting, in those with longer stump lengths.(39)

3.9 RHYTHMIC AUDITORY STIMULATION – THE CONCEPT

"Rhythm must have meaning" – Ezra Pound

Rhythm, derived from the Greek word ***Rhythmos***, is one of the core elements of any musical "language structure". It generally means "a movement marked by the regulated succession of strong and weak elements, or of opposite or different conditions".(40) For the past few decades, rhythm and music were interpreted from emotional, aesthetic and motivational points of view. It was only after studies on neurobiology of rhythm done in 1967 (Paltsev and Elner), 1976(Rossignol and Melvill) and 1980 (Ermolaeva and Borgest) (41) that a neuroscience based understanding of music was established. The rich physiological basis of sound and auditory rhythm in priming movement and the connectivity between this external sound and the motor areas in the brain were also better understood. Subsequently, interesting applications, specifically of the rhythmic structures of sound to motor rehabilitation were discovered.

Auditory rhythm has been found to affect the motor system with hierarchical connections at the primary motor cortex, premotor and supplemental cortices, basal ganglia, cerebellum, spinal pattern generators and feedback from the vestibular system.(42) Research has shown evidence that sound raises the excitability of spinal motor neurons mediated by auditory motor circuitry at the reticulospinal level.(43) This is followed by auditory projections into the cerebellum via the pontine nuclei and into striatum of the basal ganglia via the inferior colliculus and thalamic projections.(44) The striatum then projects to the output source of the basal ganglia - the Globus Pallidus which in turn sends the auditory waves to the cortical motor structures such as the supplemental cortices and pre motor cortex. Feedback comes to the basal ganglia via auditory association areas, influencing basal ganglia function in regard to sequencing and timing.(41)

Music and physiological processes (heart rate, temperature, blood pressure) are composed on vibrations which occur in a regular, periodic manner and are composed of oscillations. Entrainment follows the principle of physics whereby two objects vibrating at similar frequencies cause a mutual resonance which causes them to start vibrating at the same frequency.(45) Due to the speed and high resolution of time processing in the auditory system, external rhythm can be used to entrain body rhythm which in turn causes physiological changes in the body. The human body is also a self-correcting system with thermostat-like set point limits of simultaneity between motor rhythm and auditory rhythm.(46) Using this concept, certain properties of music have been used to promote relaxation by "entraining" body rhythm with the slower, regular external auditory rhythm.(47,48) This was seen to be effective in anxiety disorders, patients undergoing chemotherapy and operative procedures, burn patients, ICU patients and others in similar hospital settings.

3.10 STUDIES OF RHYTHMIC AUDITORY STIMULATION IN CLINICAL SCENARIOS

Rhythmic auditory stimulation as a rehabilitative measure in clinical practice has been introduced only in the recent years. As the clinical scenario of each patient differs from another, so also the impact of RAS is found to differ in various situations. A review of few studies which have looked into the clinical use and impact of music and rhythm on the brain are given below:

3.10.1 RAS GAIT TRAINING IN PATIENTS WITH HEMIPARESIS FOLLOWING CVA

A number of studies of the entrainment effect of rhythm on hemiparetic gait have been done. One of the earlier studies of rhythmic auditory stimulation for stroke patients was done by Thaut et al in 1993 on 10 hemiparetic patients four weeks to two years post stroke. After a three week training program, they reported improvement in weight bearing stance time on the paretic leg, better stride time and stride length symmetries and overall improvement in motor unit recruitment patterns reported through EMG. A smoother gait trajectory was mapped due to greater vertical displacement and lesser lateral displacement of Centre of Mass (CoM).(49) A six week training program on patients within three weeks of stroke confirmed a significant improvement in velocity (164% compared to pre-test) and stride length(88% compared to pre-test) on the paretic side but no significant improvement in symmetry.(50) There was also 30% reduction in improvement of gait parameters in those with three week training programs as compared to six week training programs which indicated that significant gains in early post stroke training can still be made after three weeks of intervention.(49)

On comparing RAS to conventional Neurodevelopmental training (NDT)/Bobath training, the gains were seen to be significantly higher in the auditory stimulation group.(51) RAS during treadmill facilitated gait training showed that musical motor feedback improved a stroke patients gait more than conventional therapy. Stride length increased by 18% versus 0%, gait symmetry deviation decreased by 58% versus 20%,velocity increased by 20% versus 4%.(52) In a study done by Ford et al. (2007) (53) focusing on RAS for the upper limb, significant improvement in gait and associated arm swing patterns was reported.

Rhythmic auditory stimulation is one of the most widely used neurologic music therapy techniques in Japan and has shown to have beneficial effects in stroke patients with lesions in the putamen, cerebellum and thalamus.(49) The comprehensive gait pattern changes after RAS training lead us to understand that it does not play just a pacemaker role but contributes to motor control hence affecting gait.

Looking at the broader application of music in this group of patients, Musical Neglect Training (MNT) is one of the topics of current interest. Here, patients are made to play musical instruments which are spatially arranged according to their neglect or arranged in chord progression such that they shift their attention from the attended visual field into the neglected field. The line cancellation and flower drawing tests as well as the frequency of collision on the side of neglect showed significant changes post intervention.(54)

Neurologic music therapy now meets the standards of evidence based medicine and is recognized by the World Federation of Neurorehabilitation.(55) It can be introduced in rehabilitation as a standard method of care.

3.10.2 RAS GAIT TRAINING IN PATIENTS WITH PARKINSONS DISEASE

Individuals with Parkinson's disease have a gait unique to the illness. Two of the most characteristic patterns of this gait are bradykinesia and shuffling stride pattern. They also have difficulty in initiating gait and turning (freezing). These gait deficits are often resistant to dopaminergic medications. Non pharmacologic approaches for improvement of mobility were encouraged. One of the earlier studies was a home based gait training program using RAS for persons with Parkinson's disease. There was a significant ($p<0.05$) improvement in their gait velocity by 25%, stride length by 12% and cadence by 10% more than self-paced subjects who improved their velocity by 7% and no training subjects whosevelocity deteriorated by 7%. Timing of EMG patterns showed a significant ($p<0.05$) change in the Tibialis Anterior and VastusLateralis muscles.(56)

3.10.3 CEREBRAL PALSY

Cerebral Palsy is a group of non-progressive movement syndromes that are characterized by motor and postural dysfunction. They result from damage to the developing brain due to various causes. In children with Cerebral Palsy, the motor cortex is damaged due to which the motor control system is disturbed. When gait pattern is not rhythmic, it is likely that the internal time keeper is malfunctioning. RAS is a promising option which helps “organize” an individuals’ gait and improve gait patterns by regulating the motor control system through stimulation of the basal ganglia, cerebellum and brain stem.(57)

One of the earlier studies was done in 1998 where seven CP children were given balance and ambulation training using rhythmic auditory stimulation. They were reported to have improved velocity, cadence, stride length and symmetry.

In 2007 another study was done comparing the effectiveness of therapist guided training and self-guided training using RAS. The therapist guided training group showed a statistically significant difference in stride length, symmetry and velocity.(57)

In 2011, a study of gait training comparing RAS and neurodevelopmental/Bobath training in twenty eight CP children reported significantly increased cadence, walking velocity, stride and step lengths with decreased anterior pelvic tilt and hip flexion during walking. The neurodevelopmental group improved significantly in internal and external rotation at the hip joints.(58)

3.10.4 MULTIPLE SCLEROSIS

Patients with this illness experience difficulty ambulating due to spastic quadriparesis and other related lower limb impairments. A study which compared therapy by walking exercise to rhythm in 10 randomly allocated patients showed improvement in gait parameters including stride and step lengths, cadence and velocity in the group with music intervention.(59)This was attributed to the fact that entrainment of beats can still occur even when areas of auditory motor regulation such as cerebellum are damaged. This is because rhythm activates different areas of the central nervous system.

No other completed studies using rhythm for ambulation training in this group of patients were found in literature.

3.10.5 SPEECH AND LANGUAGE REHABILITATION

The term Melodic Intonation Therapy (MIT) was first coined in 1973 by Sparks, Helm and Albert.(60) It was a method of communication developed for rehabilitation of stroke patients with aphasia and other language disorders. It was based on the hypothesis that the increased use of right hemispheric dominance for the melodic aspect of speech increases the role of that hemisphere in inter-hemispheric control of language, decreasing the language dominance of the damaged left hemisphere.(61) To do this, the rhythm, stress, prosody and contours of normal speech are transposed to melodic intonation patterns.

Researches which followed came up with different explanations for the improvement in speech post MIT. Evidence suggests that music may activate areas in the brain differently than speech or other stimuli do. Music enhances the way the systems work together. It activates both hemispheres of the brain-the right more than the left.(62)In 1996, Belin etal. in a study on seven non fluent aphasic patients, measured changes of cerebral blood flow in the brain during speech with and without MIT using positron emission tomography (PET). Without MIT, the right hemispheric regions were activated homotopic to that in a normal subject while the left hemisphere remained deactivated. However on repeating words with MIT, reactivation of Broca's area and the left prefrontal cortex was seen. Singing which is a function of the right hemisphere helps people produce speech by bypassing the damaged left hemisphere.(63)Hence it was concluded that music intonation played a major role in reactivation of the injured parts of the brain. The incredible plasticity potential of the brain was also noted.

In 2011, a completely different outlook on the relation between speech and melodic intonation through singing was introduced by Stahl et al. They proposed the idea that articulation may be modulated by visual or auditory rhythmic cues and that rhythm may be the neglected crucial element which was in fact decisive for speech production. Subcortical areas specifically the basal ganglia are suggested to mediate rhythmic segmentation in producing and perceiving speech. Subcortical lesions can cause loss in rhythmicity of speech. They concluded that such a group of patients would particularly benefit from rhythmic auditory stimulation of speech and that rhythmic hand tapping could have a profound impact on speech production in aphasics.(64)

In 2013, they confirmed the critical role of rhythmic pacing and formulaic language in MIT and concluded that standard therapy may engage in left perilesional brain regions while training of formulaic phrases which is known to be supported by right corticostriatal areas may open new ways of tapping into the right hemispheric language resources even without singing.(65)

3.10.6 INCOMPLETE SPINAL CORD INJURED PATIENTS

A pilot study was done on seventeen patients with incomplete spinal cord injuries having a mean age of 41years and 5.88 years post injury. No changes in gait parameters were statistically significant. At normal tempo, persons with cervical injuries improved in cadence and those with thoracic injuries improved in velocity and stride length.(66)

3.10.7 OTHER GROUPS

In certain groups of patients such as in critically ill patients in the ICUs and those with traumatic brain injuries, music was seen to be more effective for its aesthetic causes.

Critically ill patients – A majority of critically ill patients receiving mechanical ventilation survive with traumatic experiences from the ICU. Patient comfort, pain, anxiety, sleep deprivation, depression were some of the ICU symptoms studied. It was found that anxiety was alleviated by 36% in a study done on 373 ICU patients.(67) This was measured on a 100 point visual analog scale. Sedation intensity and frequency (measured by the change in dose of sedatives given) was also seen to be significantly less in the group who received music therapy.

Traumatic brain injury patients–"Neurologic Music therapy" (NMT) has been found to be effective in improving executive functions, decreasing anxiety and depression, improving emotion and mood in those with traumatic brain injury.(68)A few studies reporting the use of rhythmic auditory stimulation as a technique of NMT were found. Here, patients with debilitating and gross motor deficiencies after TBI were trained to walk. A significant improvement was seen in cadence, velocity and stride length of 7 patients who had undergone ambulation training with RAS.(69) Another study done on 8 patients with TBI reported a significant increase by 51% in mean velocity with significant improvements also in stride length(29%) and cadence (16%) and a non-significant improvement (12%) in stride symmetry.

3.11 JUSTIFICATION FOR THE STUDY

The current protocol being followed in our institute includes a two week prosthetic training program for ambulation, sensory motor function and complete independence in all activities of daily living. Rhythmic Auditory Stimulation has been researched in patients with stroke and has been found to be more effective for rehabilitation than neurodevelopmental therapy/Bobath therapy.(51) Different studies have also been done on Parkinson's Disease,(56) Cerebral Palsy(57) and Multiple Sclerosis,(59) all of which have shown positive results. In these studies, acoustic cueing has been used to improve pathological gait patterns. In stroke patients, the timing symmetry inherent in the rhythmic signal may have served as an efficient cue for the patient to achieve a higher degree of stride symmetry. In Parkinson's disease, rhythm may have acted as an external timekeeper, to which the step cadence became synchronized, helping the patient to stabilize internal time keeping and rhythm formation, giving him a steady gait.

This study is a trial to determine if prosthetic training period for amputee patients can be decreased and if gait parameters can be improved by following the same theory supporting the previous studies done on patients with Stroke, Parkinson's disease, Multiple sclerosis and Cerebral palsy.

The purpose of this study as we have stated is to determine if this method of training can decrease the period of prosthetic training and also improve gait parameters. Decreasing the prosthetic training period would be cost effective for the patients and their families. It does not restrict other therapy which can occur simultaneously. As the only intervention will be rhythmic beats which will be introduced by external sources like earphones, there are no expected side effects or adverse problems we foresee.

Since no similar study has been found on Amputee patients, this can be a useful tool for future prosthetic training in amputee patients.

4 METHODOLOGY

4.1 STUDY DESIGN

- Randomized control trial, single blinded

4.2 SETTINGS AND LOCATION WHERE THE STUDY WAS CONDUCTED

- Department of Physical Medicine and Rehabilitation, Christian Medical College, Vellore

Patients were recruited from the **Amputee clinic** held weekly in the outpatient section department. Those who satisfied the inclusion criteria were explained about the study and informed consent in their own language was obtained from those who were willing to participate.

After randomized allocation into the two groups, the concerned physiotherapistsand occupational therapists started prosthetic training in the **PT and OT sections** respectively.

The therapists assessed the endurance of walking and level of independence achieved by the patient. Following training, those patients who achieved the predefined criteria for independence were then finally evaluated in the **Motion Analysis Lab at the Rehabilitation Institute of the hospital**. The outcome measures such as Timed Up and Go, 6 minute Walk Test and analysis for the temporal gait parameters were completed in the lab.

4.3 ETHICS COMMITTEE APPROVAL

- Approval for the study was obtained from the Institutional Review Board **(Annexure 1)**
- The consent format was submitted in four different languages as expected in the population group **(English language version in Annexure 2)**

4.4 PARTICIPANTS

a. Inclusion criteria

- Unilateral transtibial amputee patients secondary to traumatic, vascular, diabetic and other causes who are ready for prosthetic training
- BMI less than 30
- Age between 18-70 years
- First time users of prosthesis
- Duration of amputation less than 5 years
- Patients with no deformities or contractures on the amputated or normal side

b. Exclusion criteria

- Patients with neurological deficits other than peripheral neuropathy
- Short residual limb, stump length < 9cm
- Patients with uncorrected auditory/visual impairment

- Patients with amputation of any other limb limiting prosthetic training
- Any other condition that limits mobility like fractures, cognitive impairment, Osteoarthritis knee

4.5 SAMPLE SIZE

32 unilateral transtibial amputee patients (16 in each arm) between the ages of 18-70 years were targeted for selection from the Amputee Clinic held in the PMR department.

METHOD OF SAMPLE SIZE CALCULATION:

Mean no. of days for prosthetic training using conventional methods (μ_1)= 14days

Mean no. of days expected for prosthetic training using RAS (μ_2)= 10days

SD = 4days

$$n = \frac{2 \times SD^2 (Z_{\alpha} + Z_{\beta})^2}{(\mu_1 - \mu_2)^2}$$

$$n = \frac{2 \times 4^2 (1.94 + 0.86)^2}{(14 - 10)^2}$$

$$= 15.68$$

Each arm n= 16

Sample Size = 32

EQUATION 4.1 - SAMPLE SIZE CALCULATION

4.6 RANDOMIZATION

4.6.1 METHOD OF ALLOCATION CONCEALMENT

Serially labelled opaque envelopes concealed randomised allocation

4.6.2 METHOD OF RANDOMISATION

Randomization was done using computer generated uniform distribution random numbers. A block size of 4 was used.

4.6.3 BLINDING

Patient could not be blinded as he would be aware of the rhythmic beats/intervention given to him. However the outcome assessor was blinded.

4.7 IMPLEMENTATION

After an initial evaluation based on the inclusion/exclusion criteria in the Amputee Clinic, individuals who satisfied the inclusion criteria were explained about the study in their own language and a written informed consent was obtained. All of them had completed pre-prosthetic training and had transtibial prosthesis fabricated before inclusion into the study.The sequence of randomisation was computer generated and allocation was concealed using opaque envelopes. Participants were given the sealed opaque envelopes in their sequence and after revealing the allocated group to the patient and therapist, they were started on prosthetic training as an outpatient.

4.8 INTERVENTION

Participants were allocated into two groups, one group receiving conventional prosthetic training (Control group), and the other group receiving the same training with additional rhythmic auditory stimulation (RAS group). Both groups were given prosthetic training and the training was considered to be completed when they attained the following criteria:

- A walking endurance of **>250m** irrespective of the cause of amputation as is currently being followed. This was inclusive of ambulation with a cane or quadripod.

- Independent transfers, activities of daily living (ADL), bus climbing, step and ramp negotiation according to the ***Rivermead Mobility Index*** (**Annexure 4**)

4.8.1 INTERVENTION GROUP

Musical cueing and rhythmic entrainment were believed to be the main properties of music effective for this group of patients. For this reason, rhythm in the form of beats was used and not music.

The amputee patients in the RAS group were given training enhanced using rhythm. The beats were made on ***Acoustica Beatcraft*** a drum machine software program on the internet.

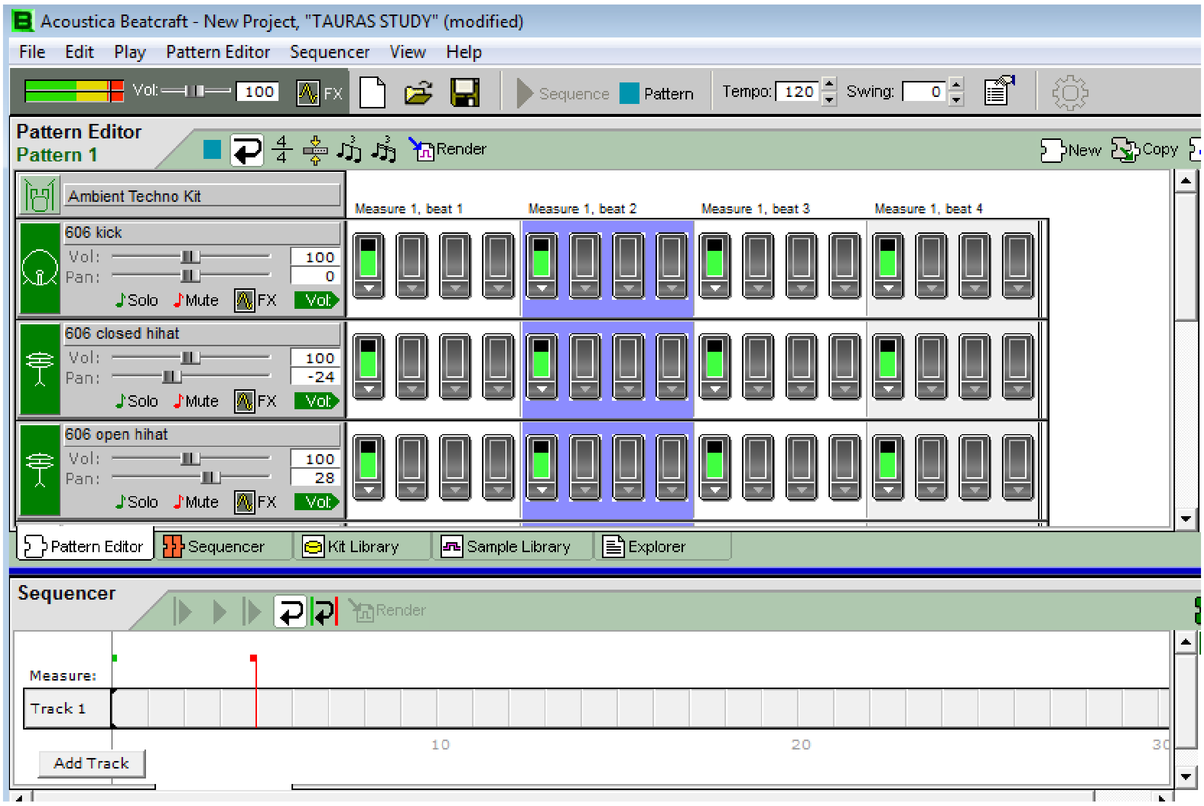


FIGURE 4.1 - ACOUSTICA BEATCRAFT SOFTWARE

The frequency of the beats ranged from 25 bpm - 120 bpm (beats per minute). These beats were delivered to the patient using mp3 players with two pairs of earphones attached to a splitter, one for the patient and the other for the therapist. Frequency was increased, decreased or retained according to the patients' abilities and compliance to follow them. In the last fifteen minutes of every hour of therapy, the earphones were withdrawn and the training consisted of no beats so as to accustom the patient to the normal gait pattern without dependence on rhythm.

Each days'session consisted of one hour in Physiotherapy for gait training, one hour in Occupational therapy for balance training and adaptation techniques to daily living. Each therapist had a one on one session with the patient recruited under him/her.

Each patient started with side to side shifting within the parallel bars and progressed to walking outside the bars with or without support depending on their degree of improvement and compliance. At every consecutive session, they directly resumed therapy from where they left off in the previous session.

4.8.2 CONTROL GROUP

This group received the same therapy without rhythm and had daily one hour of therapy each in Physiotherapy and Occupational therapy. They also had a pair of headphones without including music, beats or rhythm. This was an attempt of blinding other enrolled patients who may be undergoing training in the gym during the same time.

4.9 OUTCOME MEASURES

Outcome was analysed once the prosthetic training was completed according to the criteria mentioned above. All the outcome measures were assessed without the use of rhythm.

4.9.1 PRIMARY OUTCOME MEASURES

- **Number of hours to complete training**

Only the number of hours spent on prosthetic training was included. The time lost due to development of pressure sores or for socket modification was not included.

- **Timed up and go test (TUG)**

It is a reliable instrument with adequate concurrent validity to measure the physical mobility of patients with an amputation of the lower extremity(70)

After one practice trial which was not timed, the patient's level of functional mobility was assessed by the length of time he took to stand up from a chair (44-47cm seating height),(71) walk 3meters (10ft), walk back and sit down on the same chair. This was assessed by the gait analyst who was blinded to the intervention. It was done at the Motion analysis lab in the Rehabilitation Campus.

In a study done by Dite et al 2007,(72) the cut off for increased risk of falls in patients with lower extremity unilateral amputations was 19seconds (sensitivity 85%; specificity 74%). In community dwelling adults,(73) the cut off score was 13.5seconds (sensitivity 87%, specificity 87%).

- **6 minute walk test (6MWT)**

This is a useful measure of functional capacity in transtibial amputees. It is a reliable test which challenges an amputee's functional capacity, balance, and postural control abilities, as required in community ambulation.(74) The patients' walking endurance at a self-selected walking pace in 6minutes was calculated. This test was also completed by the gait analyst.

A study was done under the Department of Pulmonary Medicine; CMC Vellore by D.J Christopher et al.2005-2006 (unpublished) which measured the predicted value of the 6MWT in a healthy South Indian population. The predicted value was calculated using a regression equationwhichis as follows:

(7.57 x height) - (5.02 x age) - (1.76 x weight) - 309 for males

(2.11 x height) - (5.78 x age) - (2.29 x weight) + 667 for females

EQUATION 4.2 - REGRESSION EQUATION FOR 6MWT

C. Robinett et al. in their study (75) stated that the distance an individual must ambulate in order to be functionally independent in their community was about 132m to 342m.

4.9.2 SECONDARY OUTCOME MEASURES

Data was collected using observational and instrumental gait analysis.

4.9.2.1 VIDEO GAIT ANALYSIS

Patients who completed prosthetic training and who could fulfil the criteria mentioned were made to ambulate at a self-selected speed on a 22ft walk way in the motion analysis lab. Videos from anterior, posterior and both lateral views were taken. They were seen with software 'Video NAS' which was written in Visual Basic. This software could slow down the videos allowing a frame by frame observation and comparison of frames.

4.9.2.2 KINEMATICS

For **kinematic** data collection, light emitting diodes (LEDs) were attached to the bony prominences of the normal limb and the corresponding joints of the prosthesis of the amputated limb. The Phase Space apparatus automatically recorded the movement with the help of eight infrared cameras which displayed the output as 3D moving stick figures on a monitor. Using the Position Reference Structure (PRS), the position of the cameras in the room was defined from a fixed point in the room.

The following temporal gait parameters were measured. :

1. **Gait velocity** (m/min, m/sec) – This was a measure of the speed at which the patient was able to walk.
2. **Gait cadence** (steps/min) – Measured as the number of steps taken in a minute
3. **Step length** (cm)–Measured as the distance covered between the initial contact of one foot to the initial contact of the alternate foot
4. **Stride length** (cm)–Measured as the distance between heel strike of one foot to heel strike of the same foot

5. **Stance swing ratio**(%)–Measured from observational video analysis in the following way:

$$\boldsymbol{ST/a : SW/a \;=\; ST/a \times 100 : SW/a \times 100}$$

Where**ST**= No. of frames for stance; **SW** =No. of frames for swing; **a**= No. of frames for onegait cycle

EQUATION 4.3 - STANCE SWING RATIO

6. **Single limb support** – Measured as the percentage of weight bearing on a single lower limb (both normal and amputated side).
7. **Symmetry**- Calculated by the formula:

$$\frac{Step\ length\ (unaffected\ limb) - Step\ length\ (affected\ limb)}{Step\ length\ (unaffected\ limb)}$$

4.9.2.3 KINETICS

For **kinetic** data collection, recordings were made from a force plate (Kistler) camouflaged in the middle of the walkway. Using this, ground reaction forces (GRF) were measured.

The following parameters were measured (all in %):

- Vertical force
- Medial force
- Lateral force

- Forward force
- Backward force

4.9.2.4 ENERGY EFFICIENCY

Physiological Cost Index (PCI) was calculated by the formula:

$$PCI\ (beats/m) = \frac{Walking\ heart\ rate - Resting\ heart\ rate\ (beats/min)}{Average\ walking\ speed\ (m/min)}$$

All the secondary outcomes were measured by the gait analyst in the motion analysis lab who was blinded to the study and was unaware of the group the patient was in.

OBSERVATIONAL GAIT ANALYSIS

FIGURE 4.2 - RIGHT LATERAL VIEW SHOWING INITIAL CONTACT ON THE AMPUTATED SIDE

FIGURE 4.3 - LEFT LATERAL VIEW SHOWING INITIAL SWING ON AMPUTATED SIDE

FIGURE 4.4 - ANTERIOR VIEW DURING SINGLE LIMB SUPPORT ON AMPUTATED SIDE

FIGURE 4.5 - POSTERIOR VIEW DURING DOUBLE LIMB SUPPORT

INSTRUMENTAL GAIT ANALYSIS

FIGURE 4.6 - LED PLACEMENTS OVER LATERAL MALLEOLUS, BASE OF HEEL AND BASE OF LITTLE TOE ON LEFT TRANSTIBIAL PROSTHESIS

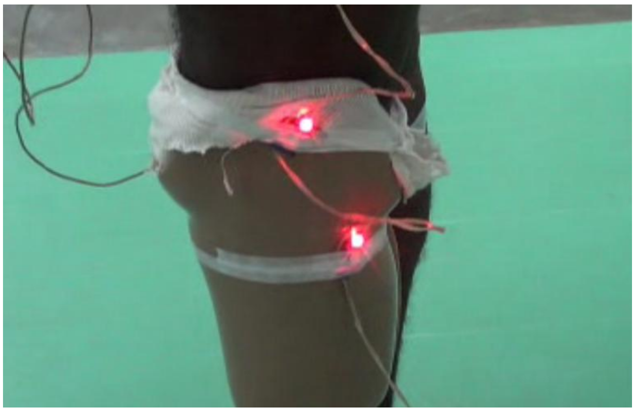


FIGURE 4.7 - LED PLACEMENTS OVER KNEE REGION ABOVE THE PROSTHESIS

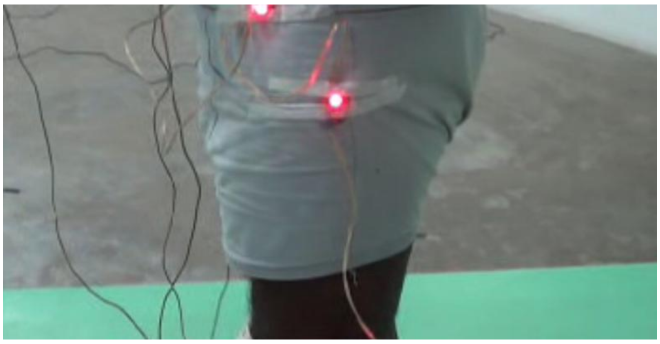


FIGURE 4.8 - LED PLACEMENTS OVER GREATER TROCHANTER

FIGURE 4.9 - PATIENT WALKING DURING INSTRUMENTAL GAIT ANALYSIS

4.10 STATISTICAL ANALYSIS

All comparisons between the groups were analyzed using the independent t-test. This test was chosen for significance with 2 tails and equal variance. To declare a test statistically significant, a level of 5% was used. The statistical software used for analysis was SPSS version 20.

5 RESULTS

44patients who satisfied the selection criteria were randomly allocated into the intervention and control groups with 24 patients in the intervention group and 20 patients inthe control group.

1 patient in each arm did not come for training. 6 patients from the intervention arm and 3 patients from the control group dropped out from the study as they could not achieve the pre-defined criteria required to complete training due to the development of ulcers. In addition 4 patients in the intervention arm discontinued training due to unknown reasons.

Outcome measurement and statistical analysis could hence be done in only 29 patients, 13 in the RAS group and 16 in the control group.

CONSORT

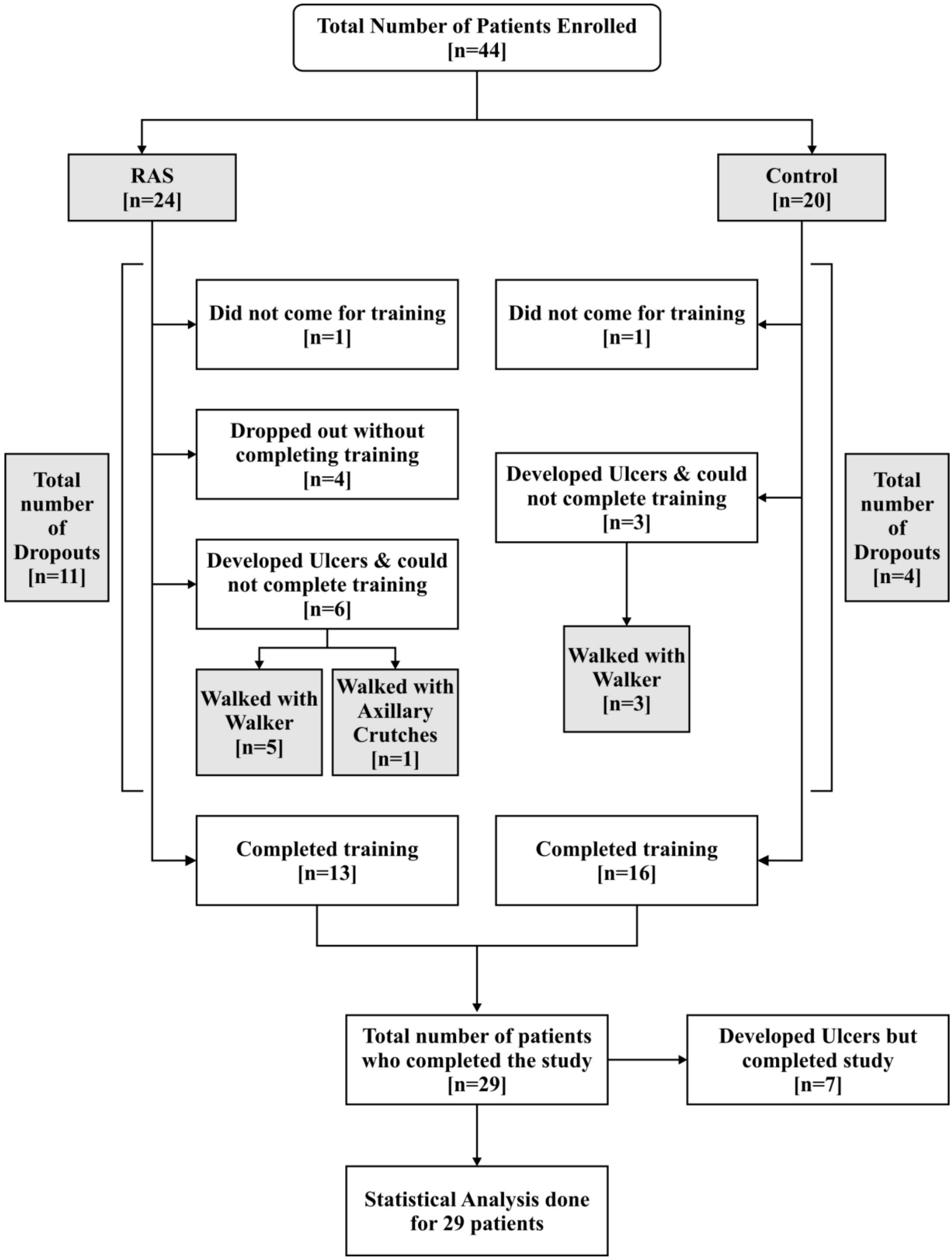


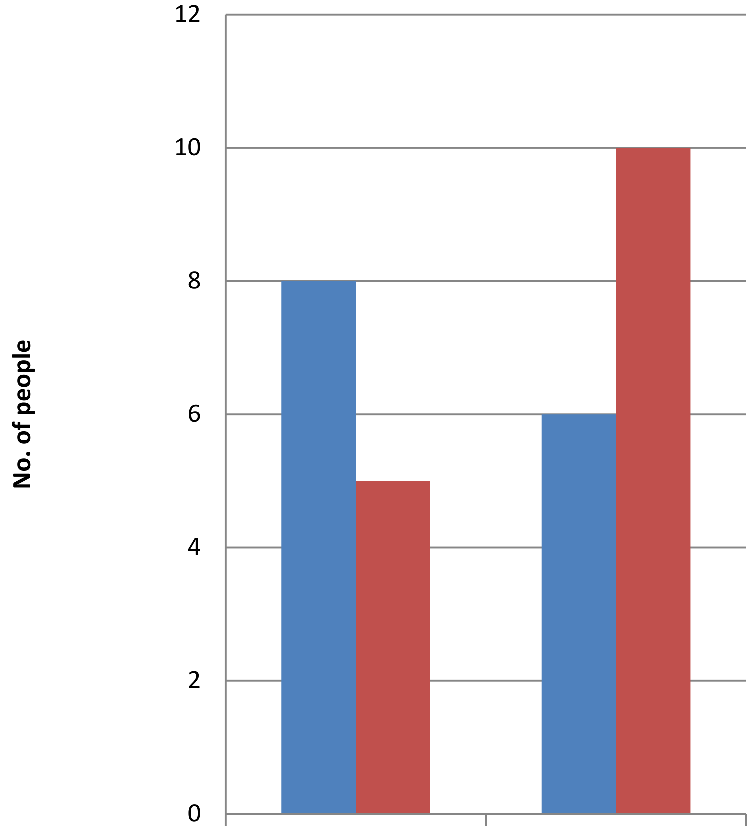
FIGURE 5.1 - CONSORT

TABLE 5.1 - SHOWING DEMOGRAPHIC DATA OF THE PATIENTS

	RAS group	Control group
Mean age (years)	46 (Range 18-65)	45 (Range 18-65)
Side of amputation (no.)		
Right	8	6
Left	5	10
Cause of amputation (no.)		
Diabetes Mellitus	3	6
RTA	8	4
Malignancies	1	1
Others	1	5
Gender (no.)		
Male	13	13
Females	0	3
Mean Height (cm)	169 (Range 161-180)	172 (Range 152-190)
Mean weight (kg)	62 (Range 40-80)	60 (Range 58-93.5)
Basal Metabolic Index (kg/m2)	22 (Range 15.06-28.55)	20 (Range 15.67-29.60)

5.1 SIDE OF AMPUTATION

The study included 29 participants who were unilateral transtibial amputee patients. There were 8 right transtibial and 5 left transtibial amputees in the intervention arm, 6 right transtibial and 10 left transtibial amputees in the control arm



	RAS	Control
Right transtibial	8	6
Left transtibial	5	10

FIGURE 5.2 - SIDE OF AMPUTATION

5.2 ETIOLOGY OF AMPUTATION

The most common cause for amputation found among our group of patients was road traffic accidents comprising of 41.38% of the causes. Second to traumatic accidents were diabetic foot due to uncontrolled Diabetes Mellitus accounting for 31.04% of the patients.Those having malignancies comprised of 6.90% and those due to other causes including infection, vascular causes, peripheral arterial occlusive disease (PAOD), blast injury and necrotizing fasciitis comprised a total percentage of 20.69%

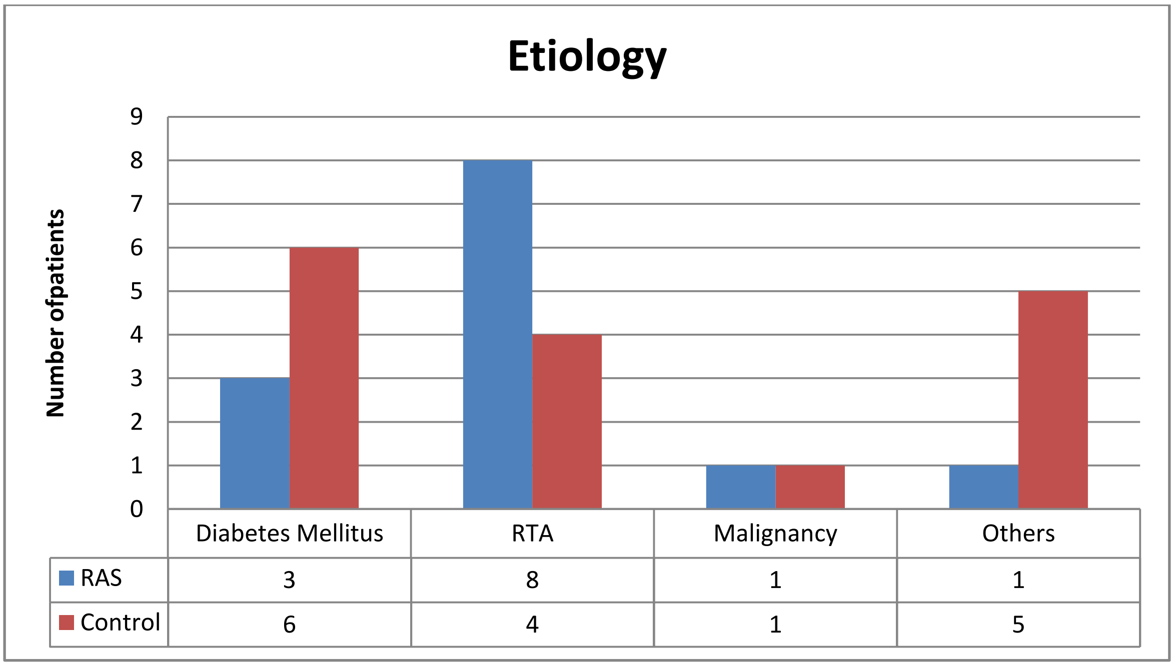


FIGURE 5.3 - ETIOLOGY OF AMPUTATION

5.3 AGE

The mean age was 46years for the intervention group and 45 years for the control group.

The numberofpatients in each age range is tabulated below.

TABLE 5.2 - DISTRIBUTION OF AGE

AGE (yrs)	**RAS**	**Control**	**Total**
Mean age(18-70)	46	45	45
<30	3 (10.34%)	3 (10.34%)	6 (20.69%)
30-50	3 (10.34%)	6 (20.69%)	9 (31.03%)
51-70	7 (24.14%)	7 (24.14%)	14 (48.28%)

The majority of the patients in our study group were above 51 years of age. The distribution of etiology to age is given in Table 5.3

TABLE 5.3 - DISTRIBUTION OF ETIOLOGY TO AGE

ETIOLOGY	**RAS**	**Control**	**Total**
Diabetes Mellitus	3 (10.34%)	6 (20.69%)	9 (31.03%)
<30 years	0	0	0
30-50 years	1	3	4
>50 years	2	3	5
RTA	8 (27.59%)	4 (13.79%)	12 (41.38%)
<30 years	2	2	4
30-50 years	2	2	4
>50 years	4	0	4
Malignancy	1 (3.45%)	1 (3.45%)	2 (6.90%)
<30 years	1	1	2
30-50 years	0	0	0
Above 50 years	0	0	0
Others	1 (3.45%)	5 (17.24%)	6 (20.69%)
<30 years	0	0	0
30-50 years	0	1	1
Above 50 years	1	4	5

5.4 GENDER

The RAS group included 13 males (100%) and had no female patients. The control groupincluded13males (81.25 %) and 3 females (18.75 %).

5.5 BMI

The mean height and mean weight of the participants in the intervention arm was 169cm and 62kg respectively.

The mean height and mean weight of the participants in the control arm was 172 cm and 60kg respectively.

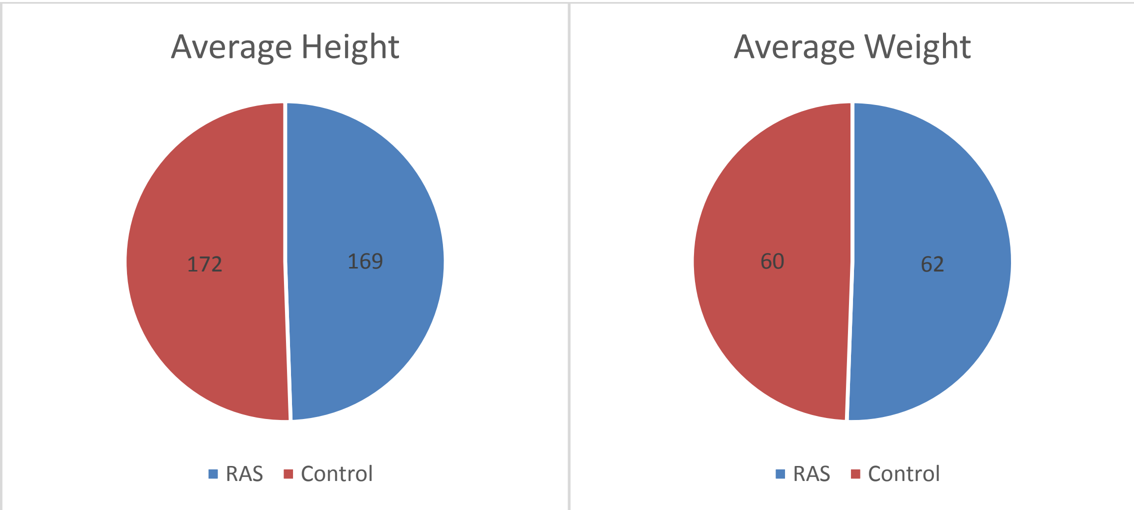


FIGURE 5.4 - AVERAGE HEIGHT AND WEIGHT DISTRIBUTION

The average BMI for the participants in the intervention arm was 22 (within normal range)

The average BMI for the participants in the control arm was 20 (within normal range)

The majority of patients were within normal weight distribution (BMI 18.5 – 22.9)

Distribution of BMI in our group of patients is seen in table 5.4

TABLE 5.4 - DISTRIBUTION OF BMI

BMI	**RAS**	**Control**	**Total**
Below 18.5	3 (10.34%)	7 (24.14%)	10 (34.48%)
18.5-22.9	5 (17.24%)	6 (20.69%)	11 (37.93%)
23-24.9	1 (3.45%)	1 (3.45%)	2 (6.9%)

5.6 SURGICAL METHODS

Two surgical methods were followed for management of the amputated limb:

Primary closure – Primary closure by posterior myocutaneous flap was done for 13patients

Secondary closure – Guillotine amputation and secondary closure was done for 12patients

4 patients did not have any surgical details available.

TABLE 5.5 - SURGICAL METHODS

Surgery performed	**RAS**	**Control**	**Total**
Primary closure by posterior flap	5 (17.24%)	8 (27.59%)	13 (44.83%)
Guillotine and Secondary closure	6 (20.69%)	6 (20.69%)	12 (41.38%)

5.7 PRIMARY OUTCOME MEASURES

5.7.1 TIME TO COMPLETE THERAPY

The patients in the RAS/intervention group took a lesser mean time of **6.08 hours** to complete training compared to those in the control group who took **7.44 hours**. This difference was not statistically significant (p value 0.159)

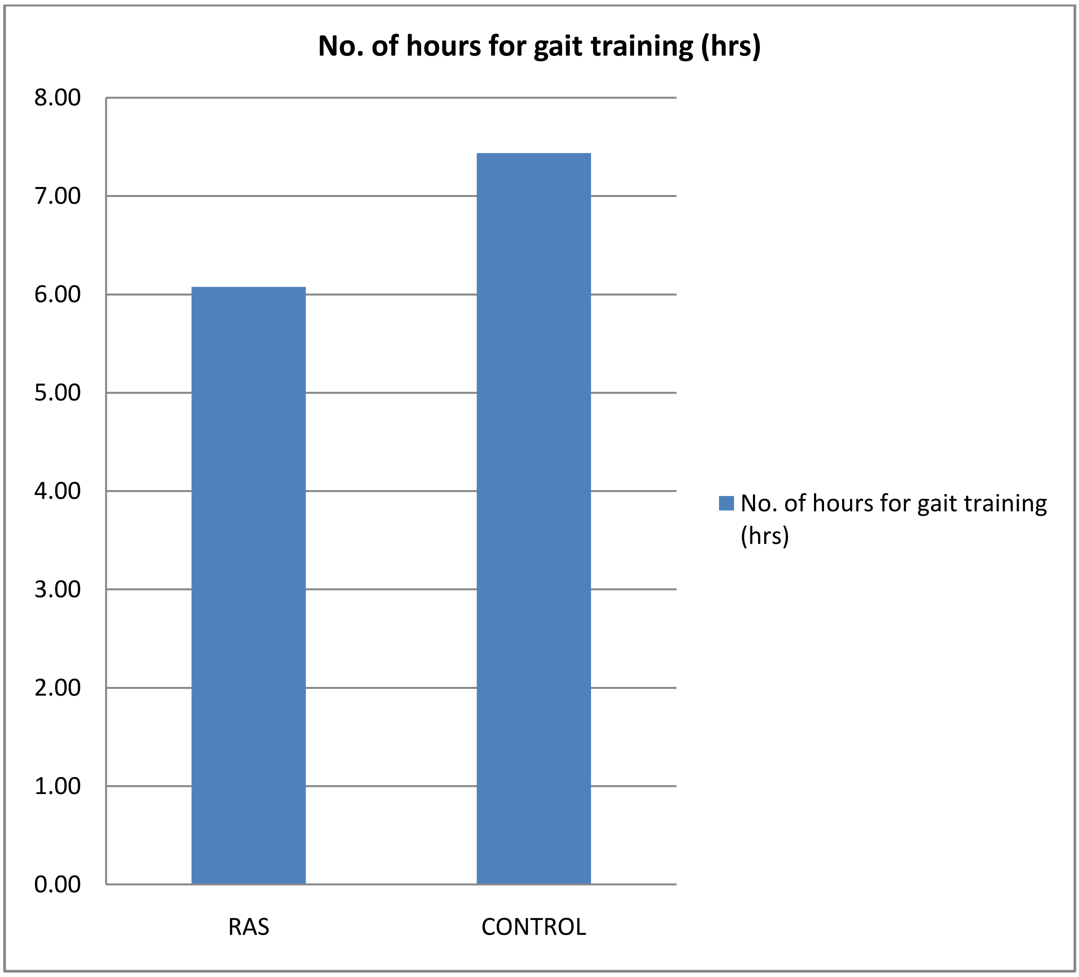
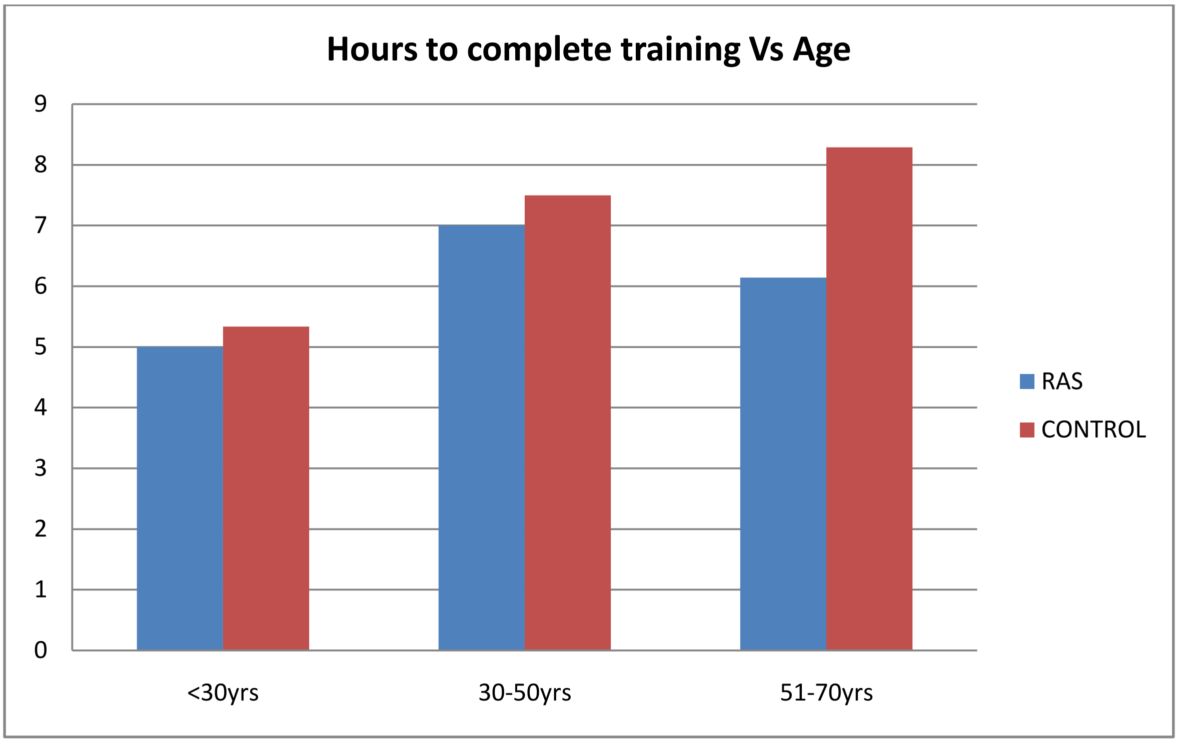


FIGURE 5.5 - NUMBER OF HOURS TAKEN TO COMPLETE TRAINING IN RAS AND CONTROL GROUPS

The period of training based on age distribution and etiology are mentioned in table 5.6 and figure 5.6

TABLE 5.6 - CORRELATION OF THE NUMBER OF HOURS TO COMPLETE TRAINING WITH AGE AND ETIOLOGY IN RAS AND CONTROL GROUPS

No. of hours for gait training (hrs)			
	RAS	**CONTROL**	**p value**
	Mean ±SD, 95% CI	**Mean ±SD, 95% CI**	
Averagehrs	6.08 ± 2.18 [4.76, 7.39]	7.44 ± 2.76 [5.97, 8.91]	0.159
Age			
<30yrs	5 ± 2.30 [3.61, 6.39]	5 ± 2.50 [4.00, 6.66]	0.722
30-50yrs	7 ±1.73 [5.95, 8.05]	8 ± 3.62 [5.57, 9.43]	0.831
51-70yrs	6 ± 2.27 [4.77, 7.51]	8 ± 2.06 [7.19, 9.38]	0.089
Etiology			
Diabetes Mellitus	6.67 ± 2.08 [5.41, 7.93]	7.5 ± 3.15 [5.82, 9.18]	0.695
RTA	5.5 ± 2.39 [4.06, 6.95]	8.5 ± 3.87 [6.44, 10.56]	0.124
Malignancy	8	4	N/A
Others	7 [5.83, 8.17]	7.2 ± 3.61 [5.28, 9.12]	0.084



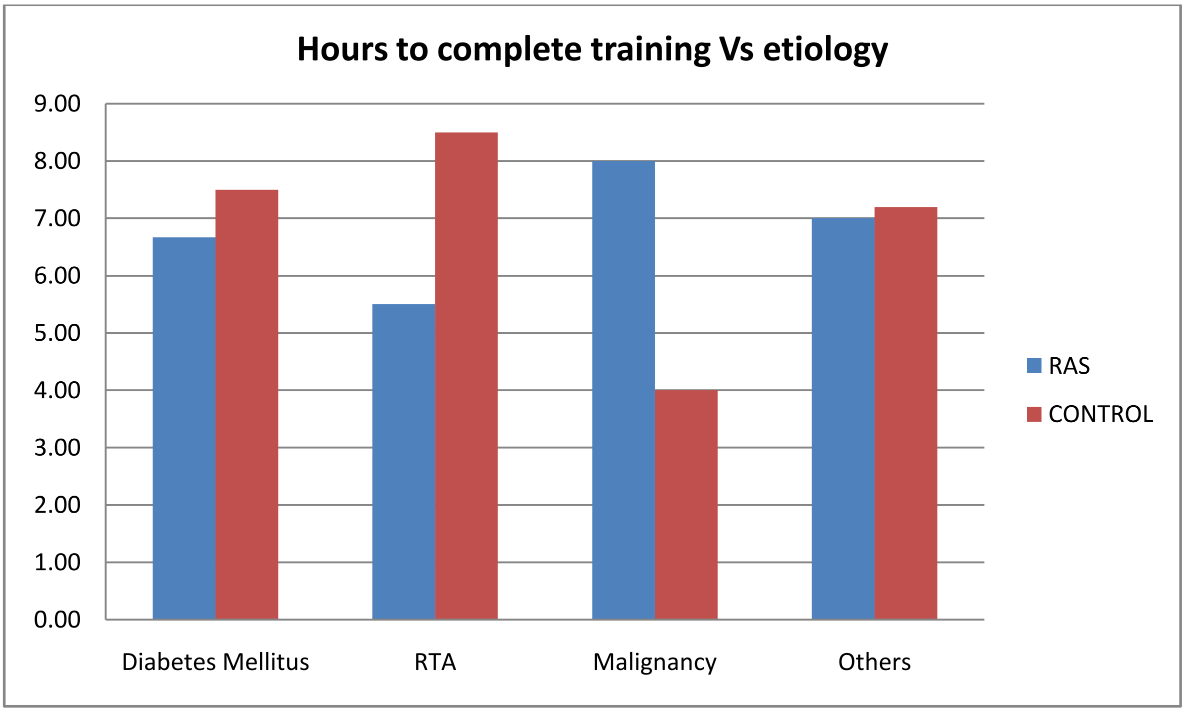


FIGURE 5.6 - RELATION OF TIME TO COMPLETE TRAINING WITH AGE AND ETIOLOGY

The average time for patients to begin prosthetic training was found to be 7 months in the intervention group and 8months in the control group. The period of training based on duration of amputation is given in table 5.7

TABLE 5.7 - RELATION BETWEEN TIME TO COMPLETE TRAINING AND DURATION OF AMPUTATION

	RAS	CONTROL
Duration of amputation below 6 months (no.)	**5**	**7**
Average hours to complete therapy (hours)	6.2	6.86
Duration of amputation between 6 months to 1 year (no.)	**7**	**6**
Average hours to complete therapy (hours)	6.57	7.67
Duration of amputation more than 1 year (no.)	**1**	**3**
Average hours to complete therapy (hours)	2	8.33

5.7.2 TIMED UP AND GO (TUG TEST)

Patients in the intervention arm completed the TUG test at a shorter average time of **11.09seconds** than those in the control arm who completed it in an average time of **13.43seconds**. This difference was not statistically significant (p value 0.061).

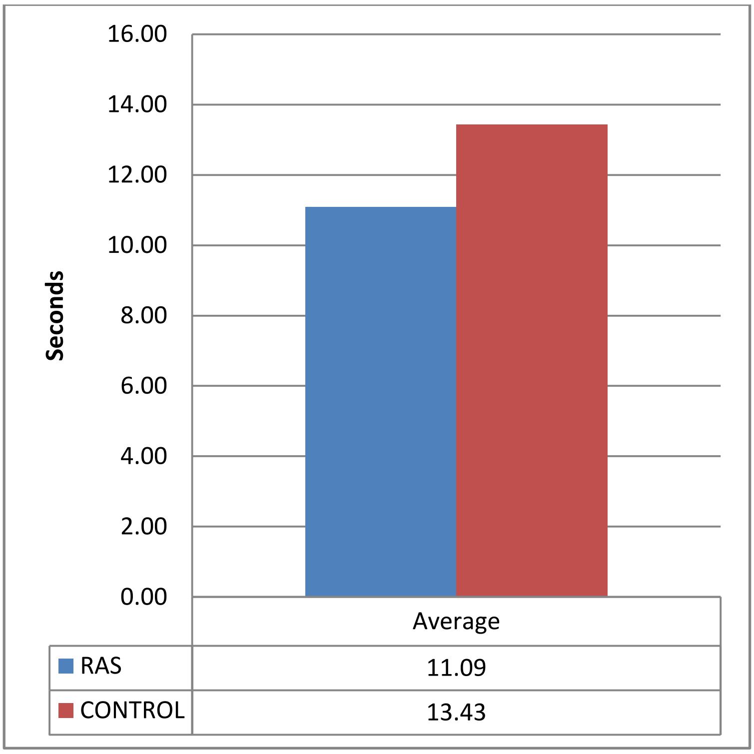


FIGURE 5.7 - TUG TEST IN RAS AND CONTROL GROUPS

Two patients with malignancy leading to amputation (1 in each group) caused significant skewing of data. On sub-analysis of TUG test excluding the skewed data, statistical significance was seen between the two groups (**p value 0.020**)

TABLE 5.8 - TUG TEST EXCLUDING SKEWED VALUES

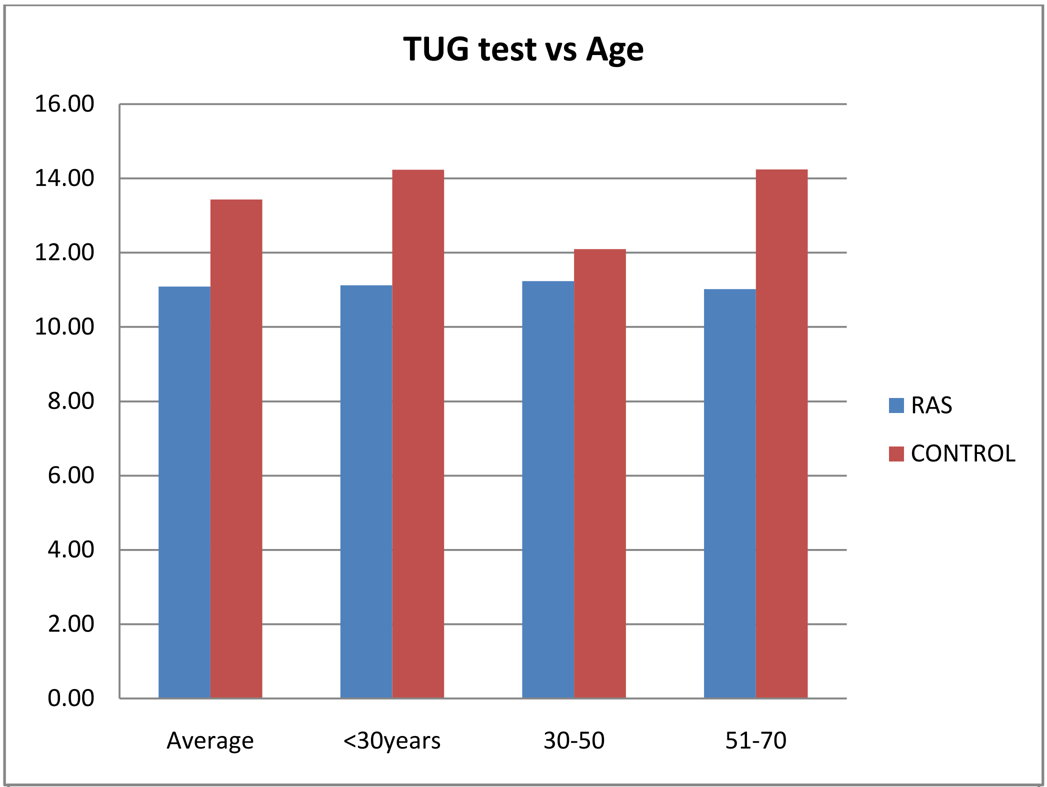
	RAS **Mean ± SD**	**Control** **Mean ± SD**	**p value**
TUG (s)	10.60 ± 1.97	13.64 ± 3.83	**0.020***

*p value<0.05 is considered statistically significant

The correlation of TUG test with age and etiology in the two groups is shown in Table 5.9 and Figure 5.8

TABLE 5.9 - CORRELATION OF THE TUG TEST WITH AGE AND ETIOLOGY IN THE RAS AND CONTROL GROUPS

	TIMED UP AND GO (secs)		
Age	**RAS** **Mean ±SD, 95% CI**	**CONTROL** **Mean ±SD, 95% CI**	**p value**
Average	11.09 ± 2.59 [9.53, 12.66]	13.43 ±3.74 [11.41, 15.46]	0.069
Age			
<30years	11.12 ± 5.01 [8.10, 14.15]	14.23 ± 7.02 [10.49, 17.97]	0.570
30-50	11.23 ±2.15 [9.93, 12.53]	12.09 ±4.98 [9.44, 14.75]	0.576
51-70	11.02 ± 1.66 [10.01, 12.02]	14.24 ± 3.91 [12.16, 16.33]	0.068
Etiology			
Diabetes Mellitus	10.33 ± 1.50[9.43, 11.24]	13.67 ±2.74 [12.38, 15.30]	0.083
RTA	10.38 ±2.07 [0.13, 11.82]	13.50 ±5.69 [10.37, 16.38]	0.218
Malignancy	17	10	N/A
Others	12.0 [10.34, 14.50]	13.60 ±4.04 [9.79, 17.42]	0.087



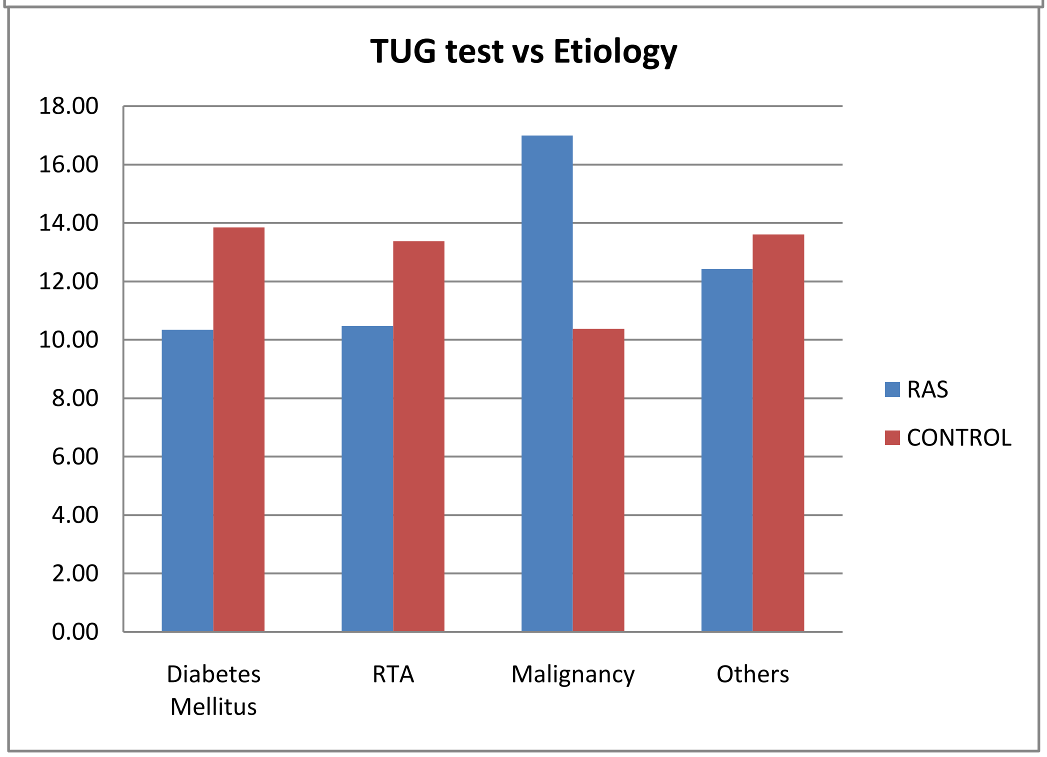


FIGURE 5.8 - RELATION OF TIMED UP AND GO TEST WITH AGE AND ETIOLOGY

5.7.3 6 MINUTE WALK TEST

The average distance covered during the 6MWT for patients in the intervention arm was**323.37m** andthis was more than that in the control arm which was **288.96 m**. This difference was not statistically significant (p value 0.390). With exclusion of the two skewed values, the p value was 0.081.

Table for 6MWT with distribution of age and etiology is given below:

TABLE 5.10 - CORRELATION OF THE 6 MINUTE WALK TEST WITH AGE AND ETIOLOGY IN THE RAS AND CONTROL GROUPS

	6 MINUTE WALK TEST		
	RAS **Mean ±SD, 95% CI**	**CONTROL** **Mean ±SD, 95% CI**	**p value**
Average	323.37 ± 115.84 [393.37, 253.37]	288.96 ± 96.25 [340.25, 237.68]	0.390
Age			
<30years	364.17 ± 169.53 [466.62, 261.72]	312.09 ± 148.17 [391.04, 233.14]	0.934
30-50	401.17 ± 80.48 [449.80, 352.53]	325.43 ± 92.27 [374.59, 276.26]	0.268
51-70	272.54 ± 61.51 [309.73, 235.36]	247.80 ± 93.66 [297.69, 197.91]	0.57
Etiology			
Diabetes Mellitus	373.33 ± 124.68 [448.68, 297.99]	246.17 ± 75.29 [286.13, 205.92]	0.092
RTA	339.63 ± 104.37 [402.76, 276.61]	346.50 ± 114.90 [407.73, 285.40]	0.919
Malignancy	135	392	N/A
Others	232 [270.63, 192.93]	273.80 ± 93.55 [351.44, 196.16]	0.081

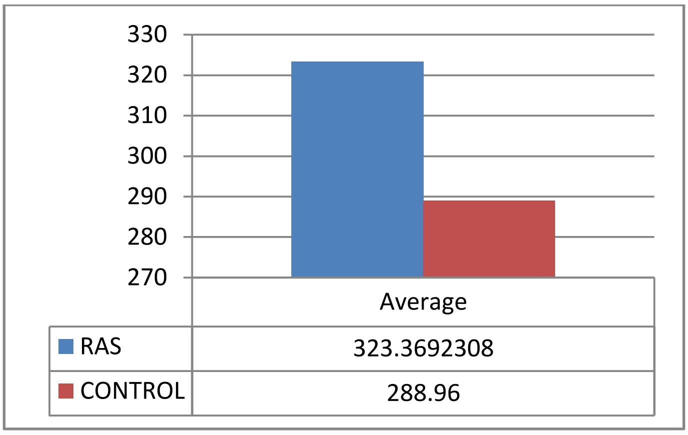
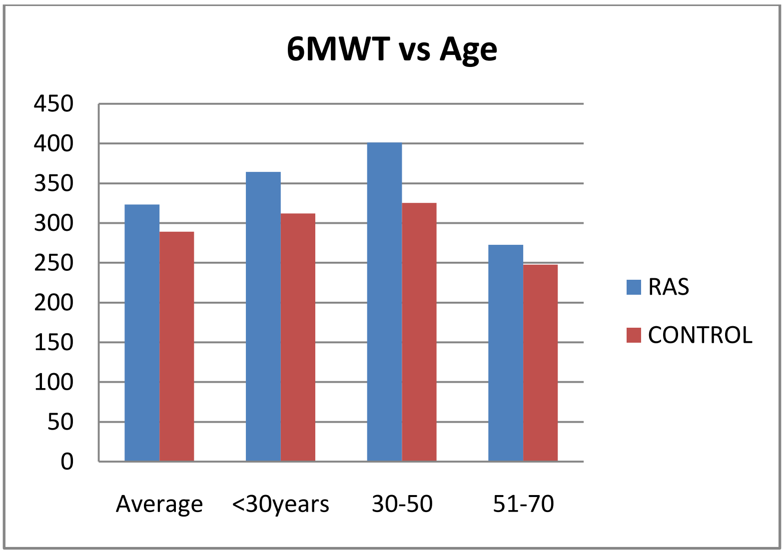


FIGURE 5.9 - 6MWT TEST IN RAS AND CONTROL GROUPS



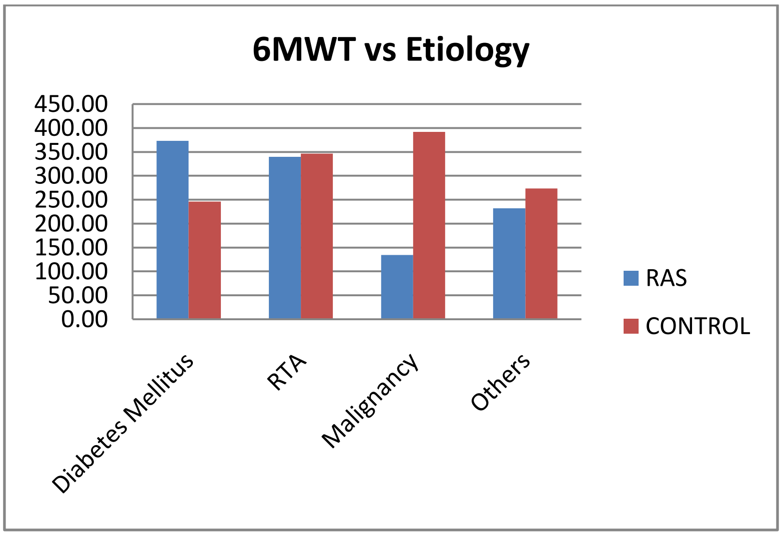


FIGURE 5.10 - RELATION OF THE 6MWT WITH AGE AND ETIOLOGY OF RAS AND CONTROL GROUPS

5.8 SECONDARY OUTCOME MEASURES

5.8.1 GAIT VELOCITY

The average gait velocity for patients in the intervention group was **45.31m/sec**, for those in the control group was **44.44m/sec**. The difference in average velocities between the two groups was not statistically significant (p value 0.881)

Gait velocity in relation to age and etiologyis given in Table 5.11 and Figure 5.11 below:

TABLE 5.11 - CORRELATION OF GAIT VELOCITY WITH AGE AND ETIOLOGY IN THE RAS AND CONTROL GROUPS

	GAIT VELOCITY (m/sec)		
	RAS **Mean ± SD, 95% CI**	**CONTROL** **Mean ± SD, 95% CI**	**p value**
Average	45.31± 15.42 [35.99, 54.63]	44.44 ± 15.53 [36.16, 52.71]	0.881
Age			
<30yrs	53.00 ± 24.21 [38.37, 67.63]	45.33 ± 21.80 [33.72, 56.95]	0.936
30-50yrs	52.33 ± 13.32 [44.29, 60.38]	48.33 ± 15.15 [40.26, 56.41]	0.711
51-70yrs	39.00 ± 8.47 [33.88, 44.12]	40.71 ± 16.70 [31.82, 49.61]	0.813
Etiology			
Diabetes Mellitus	38.33 ± 2.31 [36.94, 39.73]	41.0 ± 12.57 [34.30, 47.70]	0.735
RTA	52.25 ± 15.31 [42.99, 61.50]	48.50 ± 15.29 [40.35, 56.65]	0.697
Malignancy	22.00	65.00	N/A
Others	34.0 [28.30, 39.70]	41.20 ± 19.45 [28.86, 53.54]	0.092

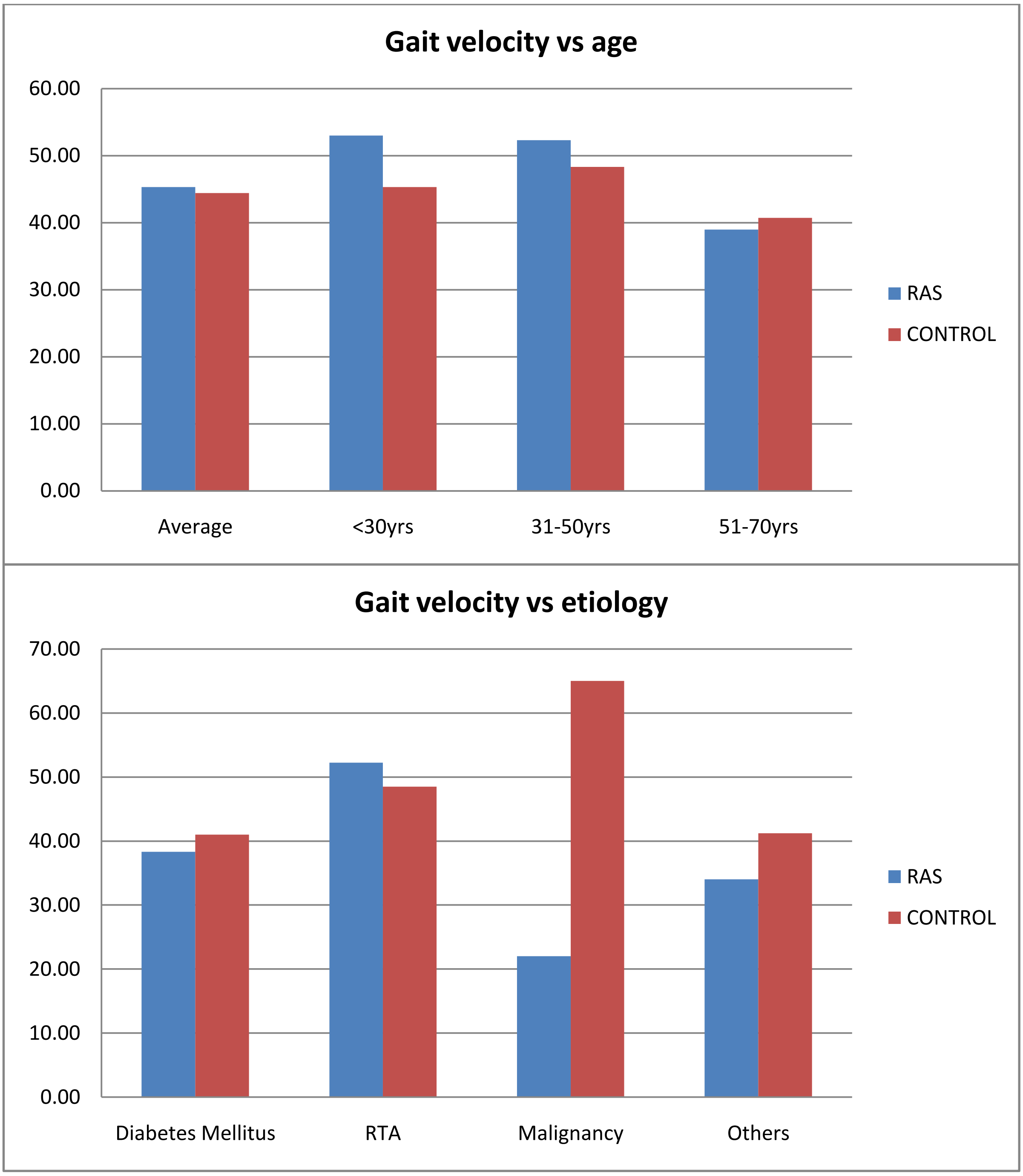


FIGURE 5.11 - RELATION OF GAIT VELOCITY WITH AGE AND ETIOLOGY OF RAS AND CONTROL GROUPS

5.8.2 GAIT CADENCE

The average cadence was **92.46steps/min** for patients in the RAS group and **96.38 steps/min** for patients in the control group. This difference was not found to be statistically significant, independent sample T test p value 0.319

Gait cadence with respect to age and diagnosis is given in table 5.12 and figure 5.12 below

TABLE 5.12 - CORRELATION OF GAIT CADENCE WITH AGE AND ETIOLOGY IN THE RAS AND CONTROL GROUPS

	GAIT CADENCE (steps/min)		
	RAS **Mean ± SD, 95% CI**	**CONTROL** **Mean ±SD, 95% CI**	**p value**
Average	92.46 ± 8.45 [87.35, 97.57]	96.38 ± 14.25 [88.78, 103.97]	0.391
Age			
<30yrs	92.00 ± 38.30 [68.86, 115.15]	91.00 ± 41.56 [68.86, 113.14]	0.780
30-50yrs	95.33 ± 5.03 [92.29, 98.38]	97.67 ± 17.22 [88.49, 106.84]	0.830
51-70yrs	91.43 ± 9.57 [85.64, 97.21]	97.57 ± 13.46 [90.40, 104.75]	0.345
Etiology			
Diabetes Mellitus	94.00 ± 12.49 [86.45, 101.55]	89.67 ± 12.61 [82.95, 96.39]	0.641
RTA	93.75 ± 7.20 [89.40, 98.11]	99.50 ± 19.0 [89.38, 109.62]	0.453
Malignancy	80.00	105.00	N/A
Others	90.00 [74.92, 105.08]	100.20 ± 50.37 [73.36, 127.04]	0.074

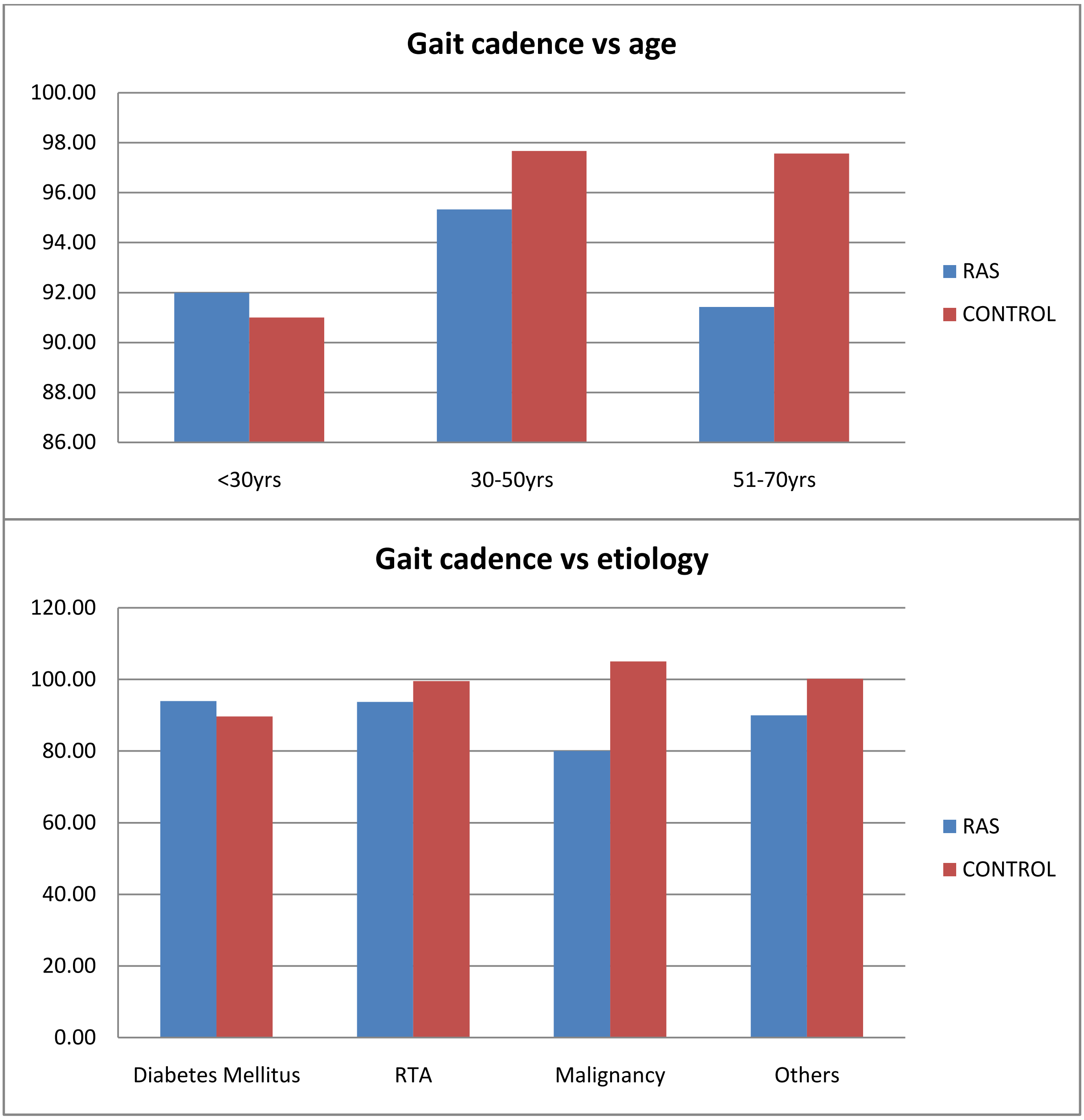


FIGURE 5.12 - RELATION OF GAIT CADENCE WITH AGE GROUP AND ETIOLOGY

5.8.3 STEP LENGTH

The step length was tabulated in both normal and amputated sides, the values of which are mentioned below.

TABLE 5.13 - CORRELATION OF STEP LENGTH OF BOTH AMPUTATED AND NORMAL SIDES IN RAS AND CONTROL GROUPS

Step length(cm)	**RAS**	**CONTROL**	**p value**
	Mean ±SD, 95% CI	**Mean ±SD, 95% CI**	
Amputated side	38.92± 6.91 [34.75, 43.10]	49.06± 12.69 [42.30, 55.82]	**0.016***
Normal side	37.62± 11.08 [30.92, 44.31]	48.69± 12.53 [42.01, 55.36]	**0.019***

*pvalue<0.05 is considered statistically significant

On comparing the intervention and control arms, the step length was lesser in the RAS group compared to control group in both amputated as well normal side and this difference was statistically significant (Independent sample T test p value **0.016** for the amputated side and **0.019** for the normal side). The step length between the amputated and normal side was also compared in both groups. Independent T test did not show any statistical significance with p values 0.72 and 0.93 for RAS and Control respectively. The difference in step length between the amputated and normal sides as a measure of symmetry is mentioned in the next section.

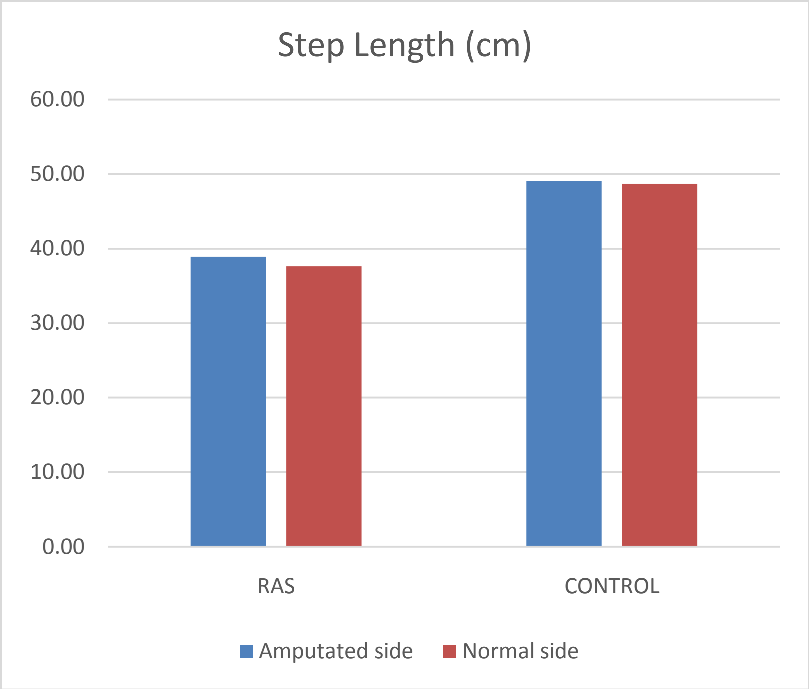


FIGURE 5.13 - STEP LENGTHS IN AMPUTATED AND NORMAL SIDES OF BOTH GROUPS

5.8.4 SYMMETRY

Symmetry of gait is a measure of step length of the affected and unaffected side. It is calculated using the following formula:

$$\frac{\textbf{\textit{Step length}}\ (\textbf{\textit{unaffectedlimb}}) - \textbf{\textit{Step length}}\ (\textbf{\textit{affectedlimb}})}{\textbf{\textit{Steplength}}\ (\textbf{\textit{unaffectedlimb}})}$$

The difference in step length between the unaffected and affected side was an average of **1.3cm** for the RAS group and **0.37cm** for the control group. With the average step length of the unaffected side taken as 37.62 for the RAS group and 48.69 for the control group, the symmetry of gait was **-0.03** for the RAS group which showed less symmetry than **-0.01** of the control group.

5.8.5 STRIDE LENGTH

Normalized stride length was compared.

TABLE 5.14 - CORRELATION OF STRIDE LENGTH OF BOTH AMPUTATED AND NORMAL SIDES IN RAS AND CONTROL GROUPS

Stride length(cm)	**RAS** **Mean ±SD, 95% CI**	**CONTROL** **Mean ±SD, 95% CI**	**p value**
Amputated side	79.62 ± 13.14 [71.67, 87.55]	97.44 ± 29.64 [81.64, 113.23]	0.055
Normal side	83.69 ± 0.17 [67.22, 100.17]	98.06 ± 27.26 [83.42, 112.70]	0.171

Stride length was greater for those in the control group though there was no significant difference between the two groups. The IndependentT test also did not show a significant difference in stride length between the normal and affected sides in patients of RAS group (p value 0.63) or Control group (p value 0.95).

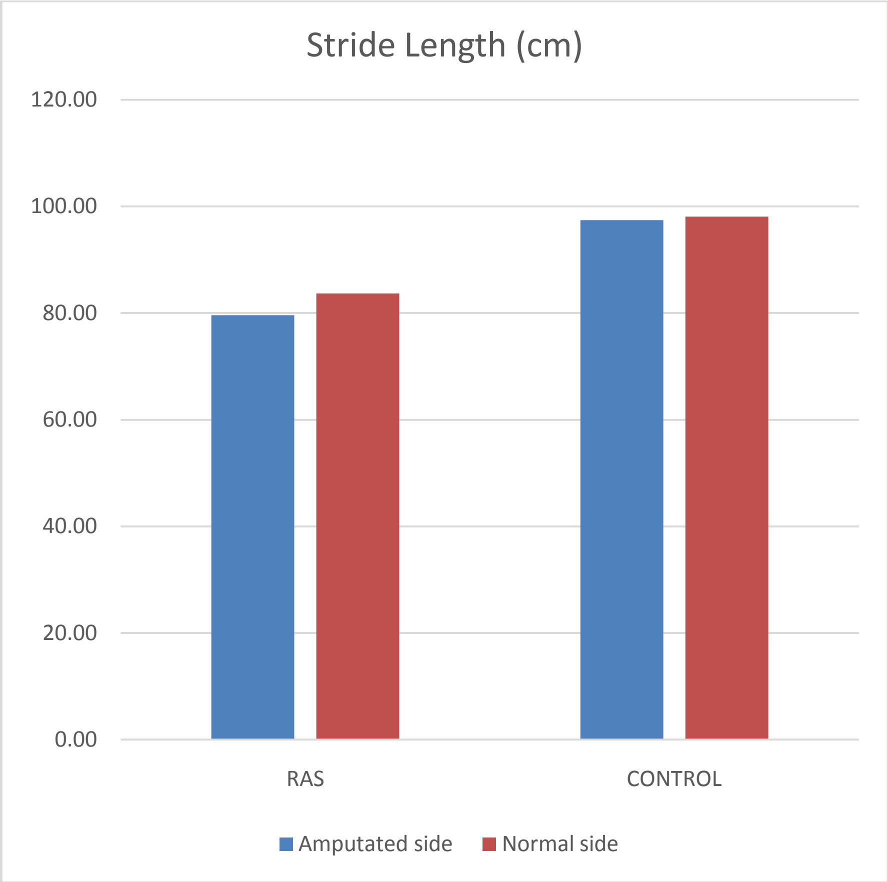


FIGURE 5.14 - STRIDE LENGTHS OF AMPUTATED AND NORMAL SIDES OF BOTH GROUPS

5.8.6 STANCE SWING RATIO

In one cycle of gait, the normal ratio of stance to swing is 60/40. The ratio of stance to swing in our patients is mentioned in the table below:

TABLE 5.15 - STANCE SWING RATIO OF THE AMPUTATED AND NORMAL SIDES IN RAS AND CONTROL GROUPS

Stance swing ratio	**RAS**	**CONTROL**
Amputated side	71/29	70/30
Normal side	74/26	74/26

5.8.7 SINGLE LIMB SUPPORT

The percentage of support on one limb in a gait cycle (SLS) is mentioned in Table 5.16 below

TABLE 5.16 - SINGLE LIMB SUPPORT OF AMPUTATED AND NORMAL LIMBS IN RAS AND CONTROL GROUPS

Single limb support (%)	**RAS** **Mean ±SD, 95% CI**	**CONTROL** **Mean ±SD , 95% CI**	**p value**
Amputated side	26.00 ±7.41 [21.53, 30.47]	26.00 ±6.84 [22.35, 29.65]	1
Normal side	29.46 ±4.58 [26.70, 32.23]	29.88 ±5.93 [26.71, 33.04]	0.838

In both groups, SLS was seen to be more on the normal side than on the amputated side.

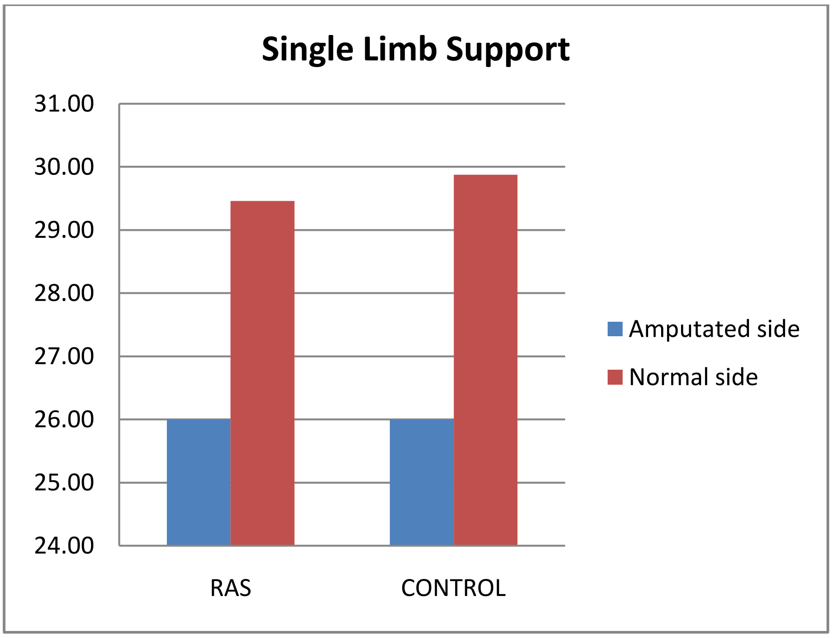


FIGURE 5.15 - PERCENTAGE OF SINGLE LIMB SUPPORT ON AMPUTATED AND NORMAL SIDE

5.8.8 ENERGY EFFICIENCY

The PCI is used as an index of energy efficiency. Those in the intervention group had an energy efficiency of 0.86 and those in the control group had 0.82. Independent T test showed no significant difference in PCI between the two groups with p value 0.833

5.8.9 KINETICS

The average taken from the kinetic parameters of 9patients is according to the table below:

TABLE 5.17 - KINETIC PARAMETERS OF GAIT

	Kinetic Parameters		
	RAS ± SD **95% CI**	**Control ± SD** **95 % CI**	**p value**
Vertical force %	95.40 ± 15.04 [86.31, 104.49]	99.20 ± 11.56 [93.04, 105.36]	0.666
Medial force %	0.20 ± 0.45 [-0.07, 0.47]	1.60 ± 2.51 [0.26, 2.94]	0.254
Lateral force %	7.60 ± 3.58 [5.44, 9.76]	7.40 ± 2.97 [5.82, 8.98]	0.926
Forward force %	5.20 ± 3.78 [2.92, 7.48]	3.20 ± 2.28 [1.98, 4.42]	0.340
Backward force %	9.60 ± 3.44 [7.52, 11.68]	7.00 ± 5.79 [3.92, 10.08]	0.413

There was no statistical significance between the kinetic parameters of the two groups

5.8.10 FREQUENCY OF RHYTHMIC BEATS USED

13 patients in the RAS group underwent training using rhythmic auditory beats. The frequency varied from 25 beats per minute (bpm) to 120 bpm. A correlation of the frequency of beats used with the three primary outcome measures was analysed. We found that those who trained with lower frequency beats completed training at a significantly shorter time (p value 0.003) than those who trained with higher frequency beats. The 6MWT was significantly better in those who trained with higher frequency beats (p value 0.001). The TUG test was shorter in those who trained with higher frequency beats though it was not statistically significant. It is summarised in table 5.18 below

TABLE 5.18 - CORRELATION OF FREQUENCY OF BEATS USED TO PRIMARY OUTCOME MEASURES

Beats used (bpm)	No. of people (n)	Hours to complete (hrs) Mean ±SD	6MWT(m) Mean ± SD	TUG(secs) Mean ± SD
25 – 50 (lower frequency)	8 (61.54%)	5.5 ± 2.98	280.91 ± 153.30	11.86 ± 6.19
51 – 120 (higher frequency)	5 (38.46%)	7± 2.55	391.3 ± 118.05	9.86 ± 1.95
p value		**0.003***	**0.001***	0.085

*p value <0.05 is considered statistically significant

On analysing the data without the two skewed values (2 patients with malignancy), the TUG was found to be statistically significant in those who trained with higher frequency beats (p value 0.037)

5.8.11 COMPARISON OF STUDY DATA TO NORMALIZED DATA

The gait parameters attained in our study were compared to normalized data of a previous study done (10 normal subjects 5-15 years of age), the values of which are tabulated below:

TABLE 5.19 - COMPARISON OF STUDY DATA WITH NORMAL DATA

Gait parameter	**Study data**		**Normal value**
	RAS	**CONTROL**	
	Mean ± SD	**Mean ± SD**	**Mean ± SD**
Gait velocity (m/sec)	45.31 ± 15.42	44.44 ± 15.53	47 ± 15
Stride length (cm)	A:79.62±3.14	A:97.44 ± 29.64	84 ± 8
	N:83.69 ±7.26	N:98.06 ± 27.47	
Stance swing ratio (%)	A: 71/29	A:70/30	60/40
	N:74/26	N:74/26	
Single Limb Support (%)	A: 26.00 ±7.40	A: 26.00 ± 6.84	40 ± 5
	N:29.46 ± 4.57	N: 29.88 ± 5.93	
PCI	0.86	0.82	0.5 ± 0.3

TABLE 5.19 (CONTINUED)

Gait parameter	Study data		Normal value
	RAS	CONTROL	
	Mean ± SD	Mean ± SD	Mean ± SD
Kinetics			
Vertical force (%)	95.40 ± 15.40	99.20 ± 11.56	115 ± 19
Medial force (%)	0.20 ± 0.45	1.60 ± 2.51	3 ± 2
Lateral force (%)	7.60 ± 3.58	7.40 ± 2.97	5 ± 2
Forward force (%)	5.20 ± 3.77	3.20 ± 2.28	17 ± 3
Backward force (%)	9.60 ± 3.44	7.00 ± 5.79	18 ± 3

A: Amputated side

N: Normal side

5.8.12 EXCLUSION OF TWO SKEWED VARIABLES

Two patients with malignancies had deranged values which skewed the results. A sub-analysis excluding these two patients showed statistically significant results in the outcome measures mentioned in table 5.20

TABLE 5.20 - ANALYSIS WITH EXCLUSION OF SKEWED VALUES

	RAS **Mean ± SD**	**Control** **Mean ± SD**	**p value**
Average TUG (s)	10.60 ± 1.97	13.64 ± 3.83	**0.020***
% decrease from regression to 6MWT (%)	45.99 ± 0.13	57.51 ± 0.14	**0.038***
Step length (cm) (Amputated side only)	39.33 ± 7.05	48.27 ± 12.71	**0.039***

For patients in the RAS group, theprimary outcome measures depending on the frequency of beats used were as follows:

RAS group			
Frequency of beats used (bpm)	**25 – 50 bpm** **Mean ± SD**	**51 – 120 bpm** **Mean ± SD**	
Hours to complete training (hrs)	5.14 ± 2.73	7 ± 2.55	**0.001***
TUG (s)	11.13 ± 5.63	9.86 ± 1.95	**0.037***
6MWT(m)	301.83 ± 157.42	391.3 ± 118.05	**0.001***

*p value <0.05 is considered statistically significant

The average number of hours to complete prosthetic training reduced for those in the RAS group from 6.08 hours to 5.92 hours whereas it increased for those in the control group from 7.44 hours to 7.67 hours. This was however not statistically significant between the groups (p value 0.081). Gait velocity increased from 45.31 m/sec to 47.25 m/sec for those in the RAS group and it decreased from 44.44 m/sec to 43.07 m/sec for those in the control group. Independent T test did not show any statistical significance (p value 0.470).For patients in the RAS group, the gait parameters which improved in the sub-analysis were 6MWT (323.37 m to 329.16 m),TUG test (11.09 s to 10.60 s), gait cadence (92.44 steps/min to 93.70steps/min), stride length of both the amputated and normal sides and physiological cost index (0.86 to 0.79). Looking at all the same parameters in the sub-analysis, patients in the control group had decreased walking distance in the 6MWT (288.96 m to 282.09 m), increased TUG time (13.43 s to 13.64 s), decreased cadence (96.38 steps/min to 95.80 steps/min), decreased stride length of both amputated and normal sides and increased physiological cost index (0.82 to 0.84).

TABLE 5.21 - ADDITIONAL ANALYSIS IN THE STUDY

Observations	**RAS**	**CONTROL**	**Total/Mean**
Total no. of patients who developed ulcers (out of 44 patients)	8	8	16
No. of patients with ulcers who completed therapy	2	5	7
No. of patients with ulcers who walked without any ambulation aids	1 (50%)	4 (80%)	5 (71.43%)
No. of patients with ulcers who walked with quadripod / cane	1 (50%)	1 (20%)	2 (28.57%)
Etiology of patients with ulcers			
Diabetes Mellitus	1	3	4
RTA	0	2	2
Others	1	0	1

TABLE 5.21 (CONTINUED)

Observations	RAS	CONTROL	Total/Mean
Amputation surgery performed			
Primary closure by posterior flap	1	0	1
Guillotine followed by secondary closure	1	3	4
No surgical details	0	2	2
Average day of training when first ulcer occurred(day no.)	2	3	2.5
Age group most prone to develop ulcers (years)	57	44	51
Average no. of days lost due to ulcers(days)	13.5	34.8	24
Average no. of days to complete therapy including days lost due to ulcers(days)	45	44.4	45

TABLE 5.21 (CONTINUED)

DROPOUTS	**RAS**	**CONTROL**	**Total/Mean**
Cause for dropouts			
Did not come for training	1 (50%)	1 (50%)	2
Walking with walker (due to ulcer)	5 (20.83%)	3 (15%)	8 (61.54%)
Walking with axillary crutches (due to ulcer)	1 (4.17%)	0	1 (7.69%)
Discontinued training	4 (16.67%)	0	4 (30.77%)
Total no. of dropouts	11	4	15

6 DISCUSSION

The aim of the study was to evaluate the usefulness of Rhythmic Auditory Stimulation to enhance prosthetic training in persons with unilateral transtibial amputation as compared with conventional therapy.

44patients were initially enrolled into our study and were randomised into two groups. 24 patients were in the RAS group and 20 were in the control group. Of the 24 patients in the RAS group, 6 developed ulcers and could not complete training to achieve the required criteria. 3 patients of the 20 in the control group similarly could not achieve the required criteria due to ulcers. 4 patients in the RAS group dropped out before they could complete training. 1 patient from each group did not report for therapy and were considered drop outs. The final number of patients who completed training according to the defined criteria was 29 that is 13 in the intervention group who received rhythmic auditory stimulation during prosthetic training and 16 in the control group who followed the conventional method of training.

The mean age of patients was 46 years in the intervention arm and 45 years in the control arm. The youngest patients were two 18 year old boys with left transtibial amputation due to road traffic accident. The oldest was a 65 year old man with right transtibial amputation due to infected diabetic foot. The most common age group for amputation was between 51 – 70 years accounting for 48.28% of all amputees. This correlated with previous studies which reported increasing incidence of amputation in ages above 60, more commonly in males.(4)The most common cause of amputation in this age group was diabetic foot.

There was a total of 14 right transtibial and 15 left transtibial amputees. The most common cause of amputation we found in our group of patients was road traffic accidents which was the cause of 12 (41.38%) of the amputations. Diabetic foot due to Diabetes Mellitus which was the cause of amputation in 9 (31.03%) patients was the second most common.This confirmed previous data which recorded the leading cause of amputation in India to bedue to road traffic accidents followed by Diabetic foot.(4)Esquenazi et al. stated that trauma related accidents including motor vehicle, industrial or farming accidents were the leading cause of amputation in developing countries.(3)The other causes of amputation were malignancies (6.90%), Peripheral arterial occlusive disease, infection, bomb blast and vascular causes (20.69%).

12 amputee patients started training within 6months after amputation, 13 patients started between 6months to 1 year and 4 patients started after 1 year. With delay in initiation of training after amputation, a minimal delay in time to completion was noticed in both groups. There was however a skewed value in the RAS group for a patient who began training after 1 year of amputation yet completed after 2 hours of therapy. This was attributed to the fact that the patient was a young 18 year old boy amputated secondary to trauma following a road traffic accident. Pohjolainenet al. stated that a time lag between surgical amputation and time to prosthetic training proved unfavourable for prosthetic usage.(76)They also reported poorer walking ability after 1year in those who waited longer to begin prosthetic training.

13(44.83%)of the patients underwent primary posterior flap closure and 12 (41.38%) underwent guillotine amputations with secondary long posterior flap closure. 4 patients did not have any surgical details available. Guillotine amputation followed by secondary flap closure has been stated to be the most common method of surgical amputation as reported in studies done by Allcock PA et al. (16) and Mooney et al(17). The major cause of amputation in our group of patientswas trauma related. Infection rates are higher in cases like diabetic foot than trauma related causes.

The primary and secondary outcome measures were calculated using the independent sample T test. In our study, we found that patients in the RAS group completed training in 6.08 hours and those in the control group in 7.44 hours. This difference however was not statistically significant with a p value of 0.159. Further studies with larger sample size may be helpful to see if there is any statistically significant difference between the two groups to complete training.

Following conventional methods, the time to complete training has usually been an average of 2weeks or 14 days (1 hour each day making it approximately 14 hours therapy time). Our aim was to complete prosthetic training in 10 hours or less using RAS. The average time to complete therapy in both groups was found to be significantly less than the conventional time for completion (6.08 hours in the RAS group, 7.44 hours in the control group). Currently we issue prosthetic training slips for a 14day period following which the patient is reviewed at the Amputee clinic for evaluation and permanent issuance of prosthetic limb. As we now see that the time frame for each individual differs, the practice of issuing therapy slips for a fixed period of 14days can be altered. The patient can resume work and return to their lives and families at the earliest. This would also be of economic benefit to the patient as he would not have to pay for extra therapy time which he may not need. Also, as a bulk of our patients come from outside the state, this would be economically beneficial to them as extra days of accommodation and rent would be avoided.

Davies and Datta in 2003stated that chances of prosthetic mobility decreased with increasing age.(31)Scremin et al. in their study stated that the rate of healing was directly proportional to age and hence related to progress in using the temporary prosthesis.(32)Pohjolainen et al. in their study (76)reported that increasing age had an unfavourable association with walking distance, walking time, amount of outdoor mobility and use of aids. In our study, correlation could be made only for those >50 years of age who were seen to have decreased walking distance and decreased walking speed compared to the younger age group. Advancing age did not seem to have a negative effect in any of the other parameters.

Time to completion analysed with diagnosis was not statistically significant in either of the groups. A few studies such as those done by Geertzen et al. (77), Davies and Datta(31) reported decreased outcome mobility scores in amputation due to vascular causes as opposed to traumatic or other causes. Munin MC et al (78) Johnson V J et al(79) clearly stated that the etiology of amputation had no influence on mobility. In our study, no significance was derived from etiology in relation to time for completion or any of the primary outcome measures or gait parameters. One 22 year old girl had undergone amputation secondary to a right calcaneal giant cell tumour. With prosthetic training in the control group, she successfully completed training in 4 hours. She did exceptionally well and had good gait parameters. The other patient with malignancy was a 28 year old man with recurrent synovial sarcoma of the left leg who 6 months after the last adjuvant chemotherapy was found to have lung metastasis. This was diagnosed only after recruiting the patient and after training had started. After recruitment into the RAS group, he did well at the start of therapy but on knowing about the prognosis, lost motivation and was unable to walk independently. He completed training in 8 hours, walking with a quadripod.

We did not derive any significant difference between the time to completion nor the gait parameters of those with Diabetes Mellitus and those who underwent traumatic amputation secondary to road traffic accidents. There was only one patient with amputation due to vascular causes who was part of the study. He was in the control group and completed training in 7 hours. The significance of this cannot be commented on in this study.

Another primary outcome measure was the timed up and go (TUG) test. Patients in the RAS group were seen to complete the TUG test in a shorter time of 11.09seconds. Those in the control group took 13.43seconds. This was however not statistically significant (p value 0.069). Age and diagnosis analysis in relation to TUG test showed shorter TUG time in the RAS group in all categories when compared with control group except forone patient with malignancy in the RAS group who took 16.99seconds as opposed to the patient with malignancy in the control group who took 10seconds. We did a sub-analysis which excluded the two patients with malignancy and found that the TUG test became statistically significant (p value 0.020). With this, we inferred that RAS could possibly be useful for improving functional mobility in the transtibial amputee patient. The usefulness of the TUG test as stated by Dite et al. 2007(72)was to predict the risk of falls and functional mobility outcome in community dwelling individuals the cut off score being 13.5s (73).

The 6-minute walking test (6MWT) was another predictor of community independence and ambulation. In our group of patients, we found that those in the RAS group walked an average of 323.37m while those in the control group covered 288.96m in 6minutes (p value0.390). This value though not seen to be statistically significant between the two groups showed that both groups of patients reached the required limit of 132m to 342m in order to be independent community ambulators as stated by C.Robinett et al.(75)The average 6MWT in all age groups was more in the RAS group than control group though none were found statistically significant. Analysis of age and etiology to 6MWT did not show any significant result. As stated earlier, only those >50 years had shorter walking endurance than those <50 years of age. In a study reported by Davies and Datta, almost all unilateral transtibial amputees less than 50 years of age attained community mobility whereas only 50% of those more than 50 years of age attained community mobility(31) which correlated with our study.

The calculated percentage decrease from the formulated regression equation to the 6MWT of our patients was48.61% for the RAS group and 57.02% for the control group. This significant drop in the 6 minute walking endurance in our patients as compared to normal individualsmay be explained by the hypothesis made by Suh-Jen lin et al.(74)who stated that impaired prosthetic balance and shorter walking endurance may be due to the decrease in muscle strength in addition to loss of voluntary ankle movement. Between the groups, the difference was not statistically significant (p value 0.134). However, on sub-analysis and exclusion of the two skewed values, this too became statistically significant with a percentage decrease from regression to 6MWT of 45.99% in the RAS group and 57.51% in the control group (p value 0.038).

Gait parameters were calculated for both groups. There was no statistical significance in the gait velocity and cadence between the two groups (p value 0.881, 0.391 respectively). In both groups, patients between 30 – 50 years of age had better cadence. It was however found that average gait cadence of those in the control group was more than those in the RAS group.We attributed this to the fact that following external cueing could bring about a systematic or forced slowing of gaitbringing about a decrease in the number of steps taken. It is possible that using higher frequency beats can overcome this setback.

There was no statistical significance in relation of velocity to cause of amputation. This correlates with earlier reports which state no significant difference in gait velocities depending on etiology of amputation.(80)Similarly, patients in the control group had significantly greater step length than those in the RAS group (p value 0.016 on the amputated side and 0.019 on the normal side). The stride length of the amputated side was also significantly greater (p value 0.055) in the control group. This was also hypothesized to be for the same reason of external cueing causing a forced reduction in step length and stride length in the RAS group.

Other gait parameters such as symmetry of gait, stance swing ratio and single limb support did not show any statistical significance between the two groups. On comparing the normal with the amputated sides, the single limb support was found to be more on the normal side than the amputated side in both groups. In the normal gait cycle, stance occupies 60 – 62% and swing occupies38 - 40% of the cycle. According to literature the prolonged duration of stance on the normal side, seen in our group of patients can be attributed to the loss of ankle plantar flexion in the prosthetic foot of amputee patients causing early toe off in the amputated limb.(81)

A pilot study was done on 10 children over a 4 month period in the motion analysis lab,CMC (1998) from which we attained our normalized data. On comparing our data to the normal values, we found that most of the parameters were compatible with the normalized data except for single limb support and stance swing ratio. This only partially coincided with earlier studies done by Robinson et al 1977;Levine1984; Saleh and Murdoch 1985 who reported thatamputees have a significantly lower walking speed as compared to normal individuals.

The symmetry in gait which is a measure of step lengths of the affected and unaffected side was not seen to be significantly different in either group.

Physiological cost index was found to have increased but still remained within normal limits for both groups without statistical significance between the two groups (p value 0.833). This confirmed the reports of YahyaSet al. who stated that physiological weight bearing and hence metabolic energy consumption was more in those with below knee amputees than in normal subjects.(82)

The kinetic parameters when calculated showed a significant decrease in forward and backward forces when compared to normalized values. This was in partial agreement with earlier studies done by Suzuki 1972; Seliktar and Mizrahi 1986; Hurley et al. 1990 where a decrease in ground reaction forces was seen in unilateral below knee amputations. The difference in gait parameters between the two groups was not statistically significant.

The relation of frequency of beats used to primary outcome measures was derived. Those who underwent training with lower frequency beats (25 – 50 bpm) were seen to have a significantly quicker time to completion of training (p value 0.003). However, those who used higher frequency beats(51 – 120 bpm) had significantly better outcomes in 6MWT (p value 0.001) and also showed better TUGresults(p value 0.085) when compared to lower frequency beats.We believe that higher frequency beats can lead to increased cadence and hence longer distance covered. However, there are more chances of forced cueing and step and stride length reduction. To overcome this, starting with low frequency beats which are comfortable to the patient and progressively increasing it to the patients' threshold while all the time maintaining symmetry would be the ideal method of training.

There were various factors which hindered therapy and delayed time to completion in many patients. One such factor was the propensity of ulcer development in most new prosthetic limb users. This was found to hinder therapy on a large scale as the patient had to avoid bearing weight on the ulcerated residual limb. In our patients, therapy was resumed only after the ulcer had completely healed.

The type of surgery performed and the development of ulcers was not found to be significantly related. Ulcers were found to form most commonly on the 2nd day after prosthetic training. The patients who developed ulcers lost an average of 24 days before they could resume training.

The causes of ulceration were narrowed down to the following reasons:

Ill-fittingprosthesis: Inadequate pressure relief on weight bearing points of the residual limb caused ulcers to develop over those areas. Using silicone sleeves were found to minimize shear forces and decrease recurrent skin lesions.(83) Socket modification helped reduce the pressure points.

Type of skin: As the skin and soft tissues of the residual limb are not as thick as that of the palms and soles, it can break down easily with shear forces and extra pressure. The rate of ulcer development was found to be directly proportional to the type of skin on the residual limb,

Low nutritional status: The normal BMI for the Indian population is within 18.5 – 22.9.(84)Majority of the patients (37.93%) had their BMI within normal range. 34.48% were underweight, 20.69% were obese and 6.9% were overweight. In our study, 4 patients (57.14%) of those who developed ulcers had their BMI within 18.5 – 22.9 and were within normal range. 2 patients (28.57%) were underweight and 1 patient was obese. As the BMI is a measure of nutritional status, this outcome did not support previous studies of

Berrdigeet al.whoin their analysis concluded that low nutritional status plays an important role in ulcer development.(22)

Wound breakdown: Primary wound healing is defined as healing of the surgical scar within the fourteenth post-surgical day. 50% of below knee amputees have failure of primary wound healing. Breakdown of scar following this period is termed as secondary wound breakdown.(85) The frequency of wound breakdown was found to depend on the location of the scar line and the protocol of wound management followed postoperatively.

Age: In our group of patients the average age group of 51 years was seen to be most prone to ulcers. This may be due to decreased nutritional status, decreased general condition, friability of skin, in addition to other factors which may cause increased chances of ulceration with increasing age.

Etiology of amputation: 57.14% of those with ulcers had undergone amputation due to diabetic foot. Such patients may have compromised peripheral vasculature leading to increased chances of ulcer formation.

Inadequate limb hygiene and care of stump leading to increased chances of ulcer formation.

The current clinical practice we follow for patients who develop pressure ulcers is to temporarily stop therapy for as long as the ulcer lasts. A study was done in 2006 by Salawu A etal.on 102 patients with prosthetic limb ulcers to associate the size of the ulcer with continued prosthetic use. It was found that despite prosthetic use, 64% ulcers healed completely and 25% ulcers decreased in size.(83) Temporary discontinuation of training due to pressure ulcers can limit activity and delay completion and patients’ return to work. In our study, the average number of days to complete training including the days lost due to ulcer formation was 45 days. Socket modification with relieving forces may enable the ulcers to heal while allowing continued use of the prosthesis. This is important to note as the time taken to complete therapy and the patients’ return to home and work can be significantly decreased by following the current international protocol of not discontinuing prosthetic training when ulcers are present. This however cannot be generalized. The stage of the ulcer up to which weight bearing can be considered needs to be further evaluated and can be a topic of further research.

Last but not the least, motivation, will power and positive attitude goes a long way in helping a patient ambulate. We observed that many of our patients who did well were optimistic and motivated. Following age, this seemed to be the next strong factor determining time to completion as well as quality of gait. However, in our study wedid not have any questionnaires which objectively measured the relation between motivation levels and time to completion. This could be considered for further research.

7 CONCLUSION

1. Patients who received prosthetic training enhanced by rhythmic auditory stimulation(RAS) completed training faster than those who underwent the training without RAS though this difference was not statistically significant.(p= 0.159). Use of RAS for prosthetic training may be helpful to reduce the training time and thereby the cost of treatment.
2. The other two primary outcome measures, the Timed Up and Go (TUG) test and 6 minute walk test (6MWT) also showed favourable results for patients under the RAS group more than for those in the control group though no statistical significance could be derived. RAS may potentially improve walking endurance and enable independent community ambulation for unilateral transtibial amputee patients. Larger studies with long term follow-up and community independence based questionnaires can be considered for future research
3. Step length was found to be significantly better for those in the control group (p=0.016 on amputated side and 0.019 on normal side) probably because of external cueing possibly leading to “forced gait” in RAS patients. The other gait parameters measured did not show any statistical significance between the two groups. Within the small sample size studied, RAS enhanced therapy could not demonstrate better gait parameters in transtibial amputee patients.

4. On doing a sub-analysis excluding two skewed values, one from each group, statistical significance was found in the TUG test ($p=0.02$)and percentage decrease from regression to 6 minute walk test ($p=0.038$) as well.
5. Patients in the RAS group were found to finish training in a significantly shorter time when they used slower frequency beats ($p=0.003$). However 6MWT of statistical significance ($p=0.001$) and better TUG($p=0.085$) was seen with the use of higher frequency beats. Further studies with larger samples may be required to establish this correlation.
6. Drop outs were mostly due to development of non-healing ulcers over the residual limb, leading to loss of several days of prosthetic training. This could be avoided by continuing weight bearing and gait training even in the presence of ulcers, as per the international protocols, along with prosthetic alteration and use of silicone liners.

8 LIMITATIONS OF THE STUDY

1. The sample size was small. The number required for statistical significance at a CI of 95% could not be achieved in the intervention arm.

2. There were a large number of dropouts the majority being due to non-healing ulcers present in the residual limbs. This caused pain and restricted ambulation and limited further progress in training.

3. Instrumental gait analysis could be completed only for 9 patients due to unresolved technical problems in the motion analysis lab.

9 SCOPE FOR FUTURE RESEARCH

1. A similar study with a larger sample size may show statistically significant results on time to completion, walking endurance and gait parameters.

2. EMG studies can be added to localize the activation of muscles and effect of ankle plantar flexion loss in the prosthetic foot causing gait changes in amputee patients.

3. Long term effects of rhythmic auditory stimulation can be analysed by introducing home based walking programmes. Level of independence and ambulation in the community can subsequently be assessed.

4. The effect of continuing prosthetic training with ulcers can be further researched. A proper guideline for continuing training with the presence of ulcer can be formulated.

5. Further studies can include questionnaires which address the effect of motivation and will power in patients who undergo training.

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11 ANNEXURE

1. Institutional Review Board Acceptance letter

2. Patient Information sheet and consent form

3. Information brochure

4. Rivermead mobility Index

5. Database with the main results

INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE
VELLORE 632 002, INDIA

Dr. George Thomas, D Ortho, PhD,
Chairperson, Ethics Committee

Dr. L. Jeyaseelan, MSc, PhD
Secretary, Research Committee, IRB

Dr. Alfred Job Daniel, D (Ortho), MS Ortho, DNB (Ortho)
Chairperson, Research Committee &
Principal

Dr. Nihal Thomas
MD MNAMS, DNB(Endo), FRACP(Endo), FRCP(Edin)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

January 7, 2013

Dr. Lahunlang Millian Sohliya
Department of Physical Rehabilitation and Medicine
Christian Medical College
Vellore 632 004

Sub: **FLUID Research grant project NEW PROPOSAL:**
Rhythmic auditory stimulation for gait training in persons with unilateral transtibial amputation – A randomized controlled trial
Dr. Lahunlang Millian Sohliya, PMR, Dr. Raji Thomas, PMR, Dr. Rohit Bhide, Dr. Apurba Barman, Mr. Lenny Vasanthan, Mr. Jebaraj Fletcher, Physiotherapy, Mr. Alok Ranjan, Mr. Paul Jebaraj, Occupational Theray, Mrs. Joyce Mary, Gait Analyst.

Ref: IRB Min. No 8129 dated 19.12.2012

Dear Dr. Lahunlang Millian Sohliya,

The Institutional Review Board (Silver, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Rhythmic auditory stimulation for gait training in persons with unilateral transtibial amputation – A randomized controlled trial" on December 19, 2012. I am quoting below the minutes of the meeting

The Committee Members raised the following queries:

1. Details of sample size and method of presenting the auditory stimulus.
2. Clearly state how the bias can be avoided when the study group has to wear a hearing gadget for the auditory stimulation.

TEL : 0416 - 2284294, 2284202 FAX : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD
CHRISTIANMEDICALCOLLEGE,
BAGAYAM, VELLORE 632002, TAMIL NADU, INDIA

Ref: FG/8129/12/2012 July 6, 2013

The Treasurer
Christian Medical College,
Vellore.

Dear Mr. Denzil,

Sub: **FLUID Research grant project:**
Rhythmic auditory stimulation for gait training in persons with unilateral transtibial amputation – A randomized controlled trial.
Dr. Lahunlang Millian Sohliya, PMR, Dr. Raji Thomas, PMR, Dr. Rohit Bhide, Dr. Apurba Barman, Mr. Lenny Vasanthan, Mr. Jebaraj Fletcher, Physiotherapy, Mr. Alok Ranjan, Mr. Paul Jebaraj, Occupational Theray, Mrs. Joyce Mary, Gait Analyst.

Ref: IRB Min. No. 8129 [INTERVEN] dated 19.12.2012

The Institutional Review Board at its meeting held on December 19, 2012 vide IRB Min. No. **8129** accepted the project *14 months for a total sanction of Rs. 46,666/- (Rupees Forty Six Thousand Six Hundred and Sixty Six only). If overspent the excess should be debited form the respective departmental or Special funds.* Kindly arrange to transfer the sanctioned amount to a separate account to be operated by Dr. Lahunlang Millian Sohliya and Dr. Raji Thomas.

Thank you.

Yours sincerely,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr Nihal Thomas
MBBS MD MNAMS DNB (Endo) FRACP(Endo) FRCP(Edin)
Secretary (Ethics Committee)
Institutional Review Board

CC: Dr. Lahunlang Millian Sohliya, Dept of PMR, CMC.
Dr. Raji Thomas, Dept of PMR, CMC.
File

PATIENT INFORMATION SHEET

Christian Medical College, Vellore

Department of PMR

A randomized controlled trial of rhythmic auditory stimulation for gait training in unilateral amputee patients

Principle Investigator- Dr. Lahunlang Millian Sohliya

Christian Medical College, Vellore

Introduction

I am Dr. Lahunlang Sohliya, working for The Department of Physical Medicine and Rehabilitation, Christian Medical College and Hospital. We are doing research on Unilateral Transtibial Amputee patients, using rhythmic auditory simulation. I am going to give you information and invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the research.

What is the purpose of the research?

Patients who have amputated limbs come to us to learn how to walk with prosthesis. We train them until they can walk by themselves. Rhythmic Auditory Stimulation is a new method which we want to use for training amputee patients to walk with their prosthesis. The reason why we are doing this research is to find out if a patient can complete training in a shorter period of time and if the walking abilities with a new prosthesis are better than the method currently being used.

If you take part what will you have to do?

This research will involve audio beats which you will need to follow as you train to walk. Your training will continue until you are able to walk on your own, without any support. When you are able to do so, some tests will be done at a gait lab, to assess your gait and the effect of the training you had.

Participant selection

We are inviting all unilateral transtibial amputee patients within the age of 15-60 years, who will be attending the Amputee clinic at PMR, to participate in the research of RAS.

Can you withdraw from this study after it starts?

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. After the study has started, you still have the liberty to withdraw out of it. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in hospital for prosthetic training.

What will happen if you develop any study related injury?

We do not expect any injury to happen, but if any unexpected problems occur due to the study, these will be treated at no cost for you. We will however not be able to provide any monetary support.

What will you have to pay for the study?

You will not need to pay for any tests which will be done for you at the end of the study. Paying for the training exercises and prosthesis however will be according to the usual protocol and concession will be given in case you are unable to pay the full amount.

What happens after the study is over?

This study may or may not have helped you complete training faster than the usual training. You will however be expected to walk independantly with your prosthesis at the end of the study.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please ask Dr.Lahunlang Sohliya or Dr. Raji Thomas (tel: 0416-2282158/ 8940068106) or email: lahunlang@cmcvellore.ac.in

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title:A randomized controlled trial of rhythmic auditory stimulation for gait training in unilateral amputee patients

Study Number:

Participant's name:

Date of Birth / Age (in years):

I____

____________, son/daughter of ______________________________________

(Please tick boxes)

Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]

I understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]

I understand that neither I, nor my doctors, will have any choice or knowledge of whether I will be in the experimental group with beats or the other group withoutbeats[ ]

I understand that I will receive free treatment for any study related injury or adverse event but I will not receive and other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date:

INVESTIGATORS' BROCHURE

Patient no.	
Patient Name	
Hospital no.	
Diagnosis	
Cause of amputation	
Date of amputation	
Date since patient last walked	

Age	
Height	
Weight	
Smoking(Y/N)	
Dominant/ Non dominant limb	
Length of residual limb	
Stump Edema	
Phantom pain/ neuroma	
Hearing(Normal/Slight impairment) - Weber's &Rinne's test	
Sight(Normal/Slight impairment)	
Comorbidities(Y/N)	

Date:	/ /201	**Day no.**		**Time**	AM/PM
Starting Frequency of beats			**Frequency of beats used**		
Steps achieved					

The Rivermead Mobility Index

Name: ____________________________

Topic and Question:							
Day							
Month							
Year							
Turning over in bed: Do you turn over from your back to your side without help?							
Lying to sitting: From lying in bed, do you get up to sit on the edge of the bed on your own?							
Sitting balance: Do you sit on the edge of the bed without holding on for 10 seconds?							
Sitting to standing: Do you stand up from any chair in less than 15 seconds and stand there for 15 seconds, using hands and/or an aid if necessary?							
Standing unsupported: (Ask to stand) Observe standing for 10 seconds without any aid							
Transfer: Do you manage to move from bed to chair and back without any help?							
Walking inside: (with an aid if necessary): Do you walk 10 meters, with an aid if necessary, but with no standby help?							
Stairs: Do you manage a flight of stairs without help?							
Walking outside: (even ground): Do you walk around outside, on pavements, without help?							
Walking inside: (with no aid): Do you walk 10 meters inside, with no caliper, splint, or other aid (including furniture or walls) without help?							
Picking up off floor: Do you manage to walk five meters, pick something up from the floor, and then walk back without help?							
Walking outside: (uneven ground): Do you walk over uneven ground (grass, gravel, snow, ice etc) without help?							
Bathing: Do you get into/out of a bath or shower and to wash yourself unsupervised and without help?							
Up and down four steps: Do you manage to go up and down four steps with no rail, but using an aid if necessary?							
Running: Do you run 10 meters without limping in four seconds (fast walk, not limping, is acceptable)?							
Total							

RESULTS				DEMOGRAPHIC DATA			
No. of hours for gait training (hrs)	RAS	Control	p value	**AGE (yrs)**	RAS	Control	Total
Average	6.08	7.44	0.159	Mean age(18-70)	46	45	45
<30yrs	5	5	0.722	<30	3	3	6
30-50yrs	7	8	0.831	%	10.34 %	10.34%	20.69 %
51-70yrs	6	8	0.089	30-50	3	6	9
				%	10.34 %	20.69%	31.03 %
Gait velocity (m/min)	RAS	CONTROL		51-70	7	7	14
Average	45.31	44.44	0.881	%	24.14 %	24.14%	48.28 %
<30yrs	53.00	45.33	0.936				
31-50yrs	52.33	48.33	0.711	**SEX**	RAS	Control	
51-70yrs	39.00	40.71	0.813	Males	13	13	26
Diabetes Mellitus	38.33	41.00	0.735	Females	0	3	3
RTA	52.25	48.50	0.697	Males %	44.83 %	44.83%	89.66 %
Malignancy	22.00	65.00	N/A	Females %	0.00%	10.34%	10.34 %
Others	34.00	41.20	0.092		RAS	Control	
				Average Height	169	172	
Gait cadence(steps/min)	RAS	CONTROL			RAS	Control	
Average	92.46	96.38	0.391	**Average Weight**	62	60	
<30yrs	92.00	91.00	0.780				
30-50yrs	95.33	97.67	0.830	**SIDE OF AMPUTATION**	RAS	Control	
51-70yrs	91.43	97.57	0.345	Right transtibial	8	6	
Diabetes Mellitus	94.00	89.67	0.641	%	27.59 %	20.69%	
RTA	93.75	99.50	0.453	Left transtibial	5	10	
Malignancy	80.00	105.00	N/A	%	17.24 %	34.48%	
Others	90.00	100.20	0.074				

				ETIOLOGY	RAS	Control	Total
Step length(cm)	RAS	CONTROL		Diabetes Mellitus	3	6	9
Amputated side	38.92	49.06	0.016	%	10.34 %	20.69%	31.03 %
Normal side	37.62	48.69	0.019	<30years	0	0	0
p value	0.72	0.93		30-50 years	1	3	4
				> 50 years	2	3	5
Stride length(cm)	RAS	CONTROL		With ulcer	1	3	4
Amputated side	79.62	97.44	0.055	%	14.29 %	42.86%	57.14 %
Normal side	83.69	98.06	0.171				
p value	0.63	0.95		RTA	8	4	12
				%	27.59 %	13.79%	41.38 %
Symmetry	RAS	CONTROL		<30 years	2	2	4
Average	-0.03	-0.01		30-50 years	2	2	4
				> 50 years	4	0	4
Stance swing ratio	RAS	CONTROL		With ulcer	0	2	2
Amputated side	71/29	70/30		%	0.00%	28.57%	28.57 %
Normal side	74/26	74/26					
				Malignancy	1	1	2
Single limb support (%)	RAS	CONTROL		%	3.45%	3.45%	6.90%
Amputated side	26.00	26.00	1	<30years	1	1	2
Normal side	29.46	29.88	0.838	30-50 years	0	0	0
				>50 years	0	0	0
PCI	RAS	CONTROL		With ulcer	0	0	0
Average	0.86	0.82	0.833765	%	0.00%	0.00%	0.00%
Complete gait analysis	RAS	CONTROL		Others	1	5	6
Vertical Force %	95.40	99.20	0.666	%	3.45%	17.24%	20.69 %
Medial Force %	0.20	1.60	0.254	<30 years	0	0	0
Lateral Force %	7.60	7.40	0.926	30-50 years	0	1	1
Forward Force %	5.20	3.20	0.340	> 50 years	1	4	5
Backward Force %	9.60	7.00	0.413				

TUG in secs	RAS	CONTROL	P value
Average	11.09	13.43	0.069
<30years	11.12333	14.23333	0.570
30-50	11.23	12.09	0.576
51-70	11.02	14.24	0.068

Diabetes Mellitus	10.34	13.84	0.083
RTA	10.47	13.38	0.218
Malignancy	16.99	10.37	N/A
Others	12.42	13.60	0.087
6MWT in meters	RAS	CONTROL	
Average	323.3692	288.96	0.390
<30years	364.1733	312.09	0.934
30-50	401.17	325.43	0.268
51-70	272.54	247.80	0.570
Diabetes Mellitus	373.33	246.03	0.092
RTA	339.69	346.57	0.919
Malignancy	134.52	392.00	N/A
Others	231.78	273.80	0.081
25-50 bpm	RAS	CONTROL	
No.of people	8		
No.of people (%)	61.54%		
Mean age	48		
Average of hours	5.5		0.003
Average TUG in secs	11.86125		0.085
Average 6MWT in meters	280.9125		0.001
51-120bpm	RAS	CONTROL	
No.of people	5		
No.of people (%)	38.46%		
Mean age	42		
Average of hours	7		
Average TUG in secs	9.862		
Average 6MWT in meters	391.3		